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Design of Ergonomic Tissue Forceps

Andrew Michael Cayer
Worcester Polytechnic Institute

Jacob Daniel Aschettino
Worcester Polytechnic Institute

Luke Paul Bogdanovich
Worcester Polytechnic Institute

Timothy Edward Granger
Worcester Polytechnic Institute

Design of Ergonomic Surgical Tissue Forceps

Sponsored by Dr. Raymond Dunn of the University of Massachusetts Medical School

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Jacob Aschettino

Luke Bogdanovich

Andrew Cayer

Timothy Granger

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Advisor: Professor Kristen Billiar

Co-Advisor: Dr. Raymond Dunn

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Authorship Page

The following paper was completed with equal contribution between all group members.

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Abstract

Current forceps lack ergonomic features and not only cause pain in the surgeon's wrist but also limit the rotational and overall manipulative ability of the tool adding time to surgery and risk of complications. To improve on the ergonomics of forceps, a novel sleeve was designed which can be placed over current forceps. Using SolidWorks and FEA we were able to modify parameters of length, diameter, and balance and validate the designs using mechanical testing. The resulting sleeve not only improves upon the rotational and manipulative ability of the forceps, but also improves overall comfort in the hand. This device reflects a more efficient movement of the hand and has the potential to decrease the time of surgical procedures and increase precision leading to fewer complications.

1.0 Introduction

Surgical complications are a big concern in the hospital setting. There are 1.7 million hospital associated infections that occur every year in the United States alone. Of these 1.7 million infections, about 99,000 cause or contribute to deaths. This results in an annual healthcare cost of $4.5 billion to $11 billion a year. Of these 1.7 million hospital associated infections 20 %, or 340,000 infections, are classified as surgical infections which means that these infections occur while during the surgical procedure (Klevens et al., 2007). It has been shown that the risk of complications, which can include infections, blood clots and longer recovery time, from surgery rise as the time spent in surgery increases (Peersman, Laskin, Davis, Peterson, & Richart, 2006). Surgeons waste time readjusting their position and angle while using hand-tools, especially forceps, which are the second most commonly used surgical tool (Dunn, 2014). Not only can this extra time being spent readjusting to these forceps lead to more complications, but it can also lead to chronic stresses and fatigue in the surgeons (Robinson & Lyon, 1994). Forceps have basic features which typically include a pair of pressed surgical steel bars that are joined at one end. Forceps are held between the thumb and index finger, when a pinch force is applied to the handle, a force is transmitted to the tip of the forceps. The tip, which is the functional part of the forceps, is used to grasp manipulate various tissues.

Even though there has been innovation in the design of the tips and specialized forceps such as laparoscopic and microsurgery, there is significant room for improvement in the handle design of forceps. Some of the weaknesses of forceps relate to the ergonomics of design. Due to forceps handles and manner they are held, traditional forceps limit the surgeon’s ability to manipulate tissue. Current forceps include a flat handle that’s purpose is to optimize the pinch force in only one plane. The problem with these forceps is not the location of where the fingers grasp the handle, but the problem is the lack of surface area available at these locations to grasp and manipulate the tool correctly. Another problem with current forceps is the lack of standardization in regards to dimensions, materials and mechanical properties. These issues lead to surgeons “recalibrating” their hands for different forceps. This can lead to longer tool usage and lack of precision in surgery. Lack of precision due to tool design can result in more in-surgery and postoperative complications such as unnecessary tissue damage or trauma, longer recovery time, and increased time of hospitalization (Mulholland & Doherty, 2006). Due to these weaknesses and the potential for improvement, there is a need for a better forceps. The main goal of our project is to design new ergonomic forceps that can rotate and move easily in the hand while still having precision and accuracy in manipulating tissue.

The main objectives of the project are improving the ergonomics, mechanical properties, standardization of design, cost and safety. The main focuses are in ergonomics of design, mechanical properties of design, and standardization of design where the design principles we use can be applied to different types of forceps. Based off these objectives our team used our research in existing literature to gain a better understanding of what is already being used and create alternative designs. Alternative designs were created in SolidWorks and tested in ANSYS before rapid prototyping. Rapid prototypes were tested by surgeons to determine the ergonomics of the design and revised designs were created based on testing. A finalized design was created based off of the best balance between ergonomics and mechanical properties.

2.0 Literature Review

2.1 Importance

There has been limited innovation in forceps design and this has limited the functionality of forceps. The changes that have been made to the design of tissue forceps are focused mainly on the teeth configuration at the tip and the overall variation in lengths. Figure 1 shows a range of these teeth and size sets.

Figure 1: Tissue forceps with varying teeth (www.medword.com)

The patents published in later sections of this paper will show that there has been little standardization in the design of different tissue forceps across the market. The surgeons at University of Massachusetts Medical School (UMass Medical), along with Dr. Dunn are looking to aid our group in the design of a pair of tissue forceps that will include concepts of ergonomics that can be applied to multiple sets of forceps that have different lengths, teeth, weights, etc.

In looking at the forceps used at UMass, there is no "common" type that is used in surgeries because there are so many specialized procedures that require very specific tools. In spite of the wide range of types of forceps being used by hospital staff, we do find that for the most part they are made of surgical steel and are cleaned using autoclaving equipment. Surgical steel is the material of choice for many surgical instruments because of its durability and allowance for sterilization methods such as autoclave.

2.2 Anatomy of the Hand

In order to understand how to design a new tissue forcep to have a more ergonomic fit to the hand, one has to understand the underlying structure and mechanics of the hand. The human hand is a complex arrangement of muscle tissue, ligaments, and small bones. The two bones of the lower arm, the radius and ulna, meet the hand and form the wrist. From here the hand is comprised of bones called carpals, metacarpals and phalanges. There are 27 of these highly specialized bones that make up the human hand.

The Median and Ulnar nerves run along the top side of the hand and branch into the palm and fingers. These, along with other nerves in the lower and upper arm, are responsible for transmitting impulses from the brain to the muscles to control movement (Chamagne & Tubiana, 2005).

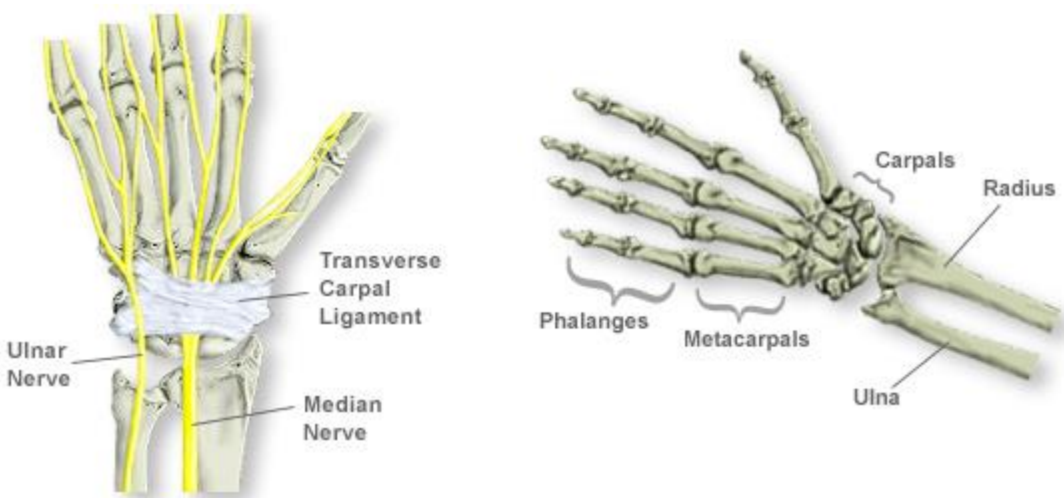


Figure 2: Bone and nerve diagram of hand

The muscles of the hand are split into two groups. One is the intrinsic, which are the muscles located in the hand itself. The other is extrinsic, which are located proximally in the forearm and stretch into the hand via long tendons (Wilhelmi & Marrero, 2013). The intrinsic muscles are mostly responsible for controlling the movement of digits and the thumb, whereas the extrinsic muscles are used for positioning of the wrist and hand rotation.

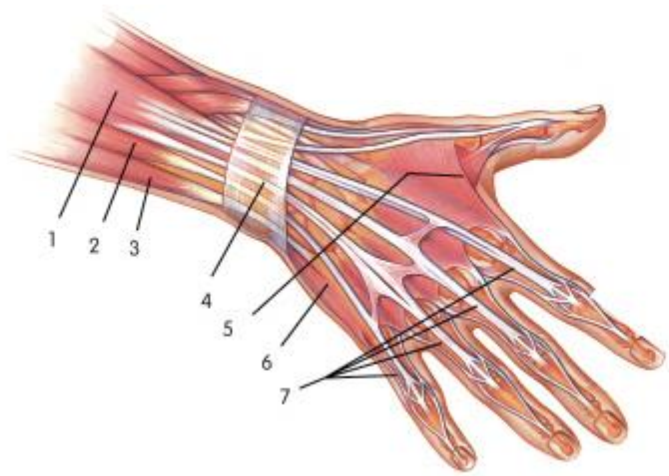


Figure 3: Muscle arrangement in the hand

2.3 Ergonomics

The main objective of our project is to improve the design of surgical forceps to be more ergonomic. First, we must define ergonomics as the, “the process of changing the work environment (equipment, furniture, pace of work, etc.) to fit the physical requirements and limitations of employees rather than forcing workers to adapt to jobs that can, over time, have a debilitating effect on their physical well-being" ("Ergonomics," 2007). In the scope of our project we are looking to change the ‘equipment’, or forceps in this case, to fit a surgeon better than the current model on the market. If the surgeon is developing debilitating health issues in his upper extremities due to the need for him/her to compensate for the limitations of the tool, his/her performance in surgery will suffer over time. If more time is needed in surgery due to a physical discomfort issue with the surgeon or the surgical procedures are lengthened or otherwise compromised, the chance of infection and other postoperative complications increases rapidly. This doesn’t just affect the patients, but the hospital as well in terms of patient recovery after procedures and liability for poor quality of care.

Taking the idea of improving ergonomics, usually applied to the work place, and applying it to the operating room is something that hasn't been done much in the past, specifically in the surgical tools used. The lack of innovation over the years, especially in forceps design, is shocking. Dr. Adrian Park a laparoscopic surgeon argues that, "if operating rooms received the kinds of work-site ergonomic inspections that manufacturing facilities are subjected to, the surgical work space would be shut down" (Reiling, 2009). Since there is this void in operating room ergonomics, we need to look elsewhere to find design improvement in similar areas to small, precise hand tools for reference.

A study was done to analyze the effect of tool handle shape on hand muscle load and pinch force during a simulated dental scaling task. Carpal tunnel syndrome is a muscular disorder that is common amongst dentists and dental hygienists. Eight different 'custom-designed' dental scaling instruments were created. In a tooth scaling exercise, 24 dentists and hygienists used all eight instruments. According to the study, "The muscle activity of two extensors and two flexors in the forearm was recorded with electromyography while thumb pinch force was measured by pressure sensors. The results demonstrated that the instrument handle with a tapered, round shape and a 10 mm diameter required the least muscle load and pinch force when performing simulated periodontal work" (Dong et al., 2007). Looking more closely into the testing methods and parameters used to design and create these tools will allow us to apply similar methods to our project with forceps. While this test quantitatively assesses the issues of ergonomics in precision medical hand tools, receiving feedback from operators about hand tools provides important information about the qualitative value of design alternatives. Simulating a work environment in which the ergonomics of a hand tool such as tissue forceps is very difficult due to the procedural and regulatory policies of hospitals as well as the demand for the operator's undivided attention during a surgical operation. The work environment being an operating room makes it very difficult to simulate a surgery for a surgeon with our models. Developing a proper testing and evaluation method for our future models will be important in identifying the best properties, mechanical and material, for the final design.

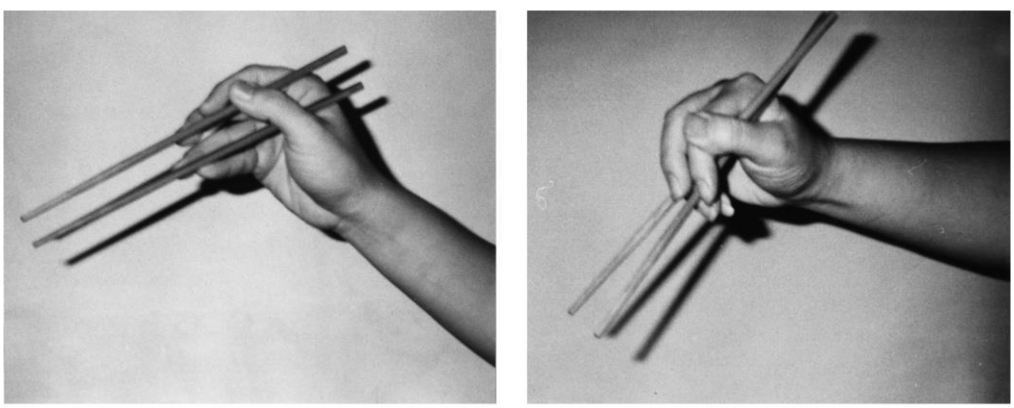
2.4 Ergonomic Relations of the Hand

Ergonomics, as it relates to this project is concerned with design of a pair of forceps that increase productivity and ease of use for the user. The design of any hand tools requires attention to details such as weight, fit, and balance but must also address how the tool will be used to complete specialized tasks ("Hand Tool Ergonomics- Tool Design," 2013). Incorporating all of these factors into consideration for the design of a new pair of forceps is imperative to developing an innovative design that facilitates ease of use for surgeons.

To dive deeper into ergonomics and how it is applied to common hand tools used every day, we will look at the ergonomics of a pen. As you know pens come in many different shapes, sizes and all contain different features. For example there are many types of pens that are flat or very skinny in diameter, such as a standard Bic pen. These types of pens often cause discomfort in the wrist and hand when used for a long period of time. On the opposite side there are very ergonomic pens that include many different features that allow them to be used for a longer period of time without causing discomfort. Usually these pens are a little longer and thicker which creates a more comfortable weight distribution. These pens also include many grip features that allow the fingers to grip the pen easier and reduce slipping. Many of these grips are made of a different, softer material than the rest of the pen and also have a certain shape which allows the user to rest their fingers in a certain position intuitively.

Figure 4: Ergonomic vs Standard Pen (www.bicworld.com)

With respect to our project, we decided to look closely at related products and how attempts have been made to improve them ergonomically. For example we looked at the ergonomics of chop sticks. More specifically, a study that was done to improve the shape of chop sticks. The study focused on two forms of gripping the chopsticks which were scissor-pinching and pincer-pinching. Pincer-pinching is very closely related to the posture that surgeons would be using to hold forceps during a surgical procedure (Chen, 1998). Also this grip proved to have higher accuracy and stability throughout the experiments conducted. The subjects were college students and had to perform a series of tasks that are closely related such as picking up small pieces of food and maneuver them. Six different chopsticks were used with a mixture of round or square handles paired with round or square tips. The study suggested that out of both the pincers-pinching and scissor-pinching groups the combination of the round tip and the round handle with grooves to grip was the most favorable. The results were based off of the student's feedback on comfort, grip ease, arm not aching, and the force exertion necessary feasibility. The objective of this study very closely resembles the objective of our project, which are very focused on ergonomics of design.



Pincers-pinching   Scissors-pinching

Figure 5: Pincers-pinching and scissors-pinching technique to hold chopsticks (Chen, 1998)

2.5 Patent Search

A patent search was conducted on forceps to determine the advancements in forceps technology focusing on ergonomic improvement. Patents were divided into two sections, traditional forceps and forceps grips and handles. Traditional forceps were defined as forceps that were similar to the earliest forceps designs and had little to no improvement in what we defined as ergonomic function. The forceps grips and handles section focused on designs that improved ergonomic design either through the design of a grip, handle or both. A total of 15 patents were examined for this project.

2.5.1 Traditional Forceps

Traditional forceps refer to the earliest set of patent designs. Most patents consist of two blades/ beams with the jaws at the distal end and the blades connected at the proximal end when held in the hand. Forceps are made of an elastic material and developed in a manner so that there is a gap between the jaws of each blade. Traditional forceps are similar in design to the forceps shown in figure five. (Hanlon, 1965; Porat & Porat, 1991; Tartaglie, 1982)

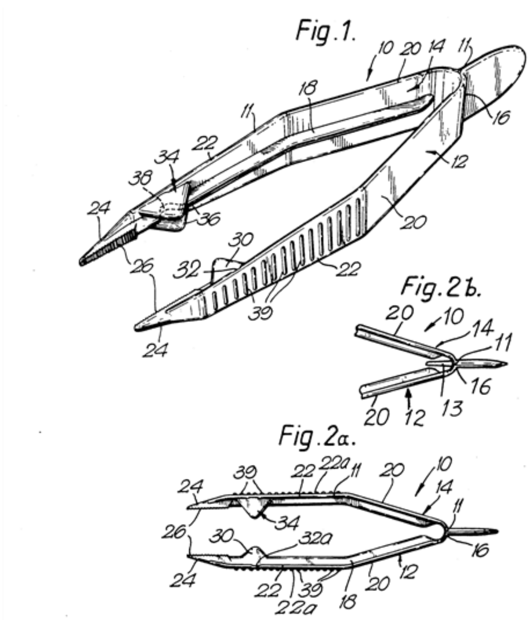


Figure 6: Plastic Forceps Design (Porat & Porat, 1991)

Traditional forceps typically are not different in shape or function but in material choice and how they are manufactured. In regards to material choice, forceps are usually made of a metal, such as stainless steel, or a plastic. Stainless steel forceps are reusable because they are capable of going through the sterilization process while plastic forceps are typically for disposable use. Some of the slight modifications include the integration of holes in the blades of the forceps and the ability to flatten into one complete piece. The hole in the forceps blade in one patent was designed for the use of a needle holder for suturing. These suture forceps are designed to be used while suturing the skin, where the hole and the design of jaws give a better grip to grab suture needles. This helps because of less slippage and damage to the tissue upon removal of the needle from the skin. This is one modification to forceps that has no major effect on any functionality of forceps as far as how they manipulate tissue. (Godfrey, 1950; Holohan, 1962; Lahay, 1980; Wannag, 1977)

2.5.2 Forceps Grips and Handles

When dealing with forceps grip and handle patents there is not much focus on redesigning individual forceps, but more of the focus lies on developing a “sleeve” or mountable type structure that allows the user to have better control or feel for the instrument.

Grips are developed so that there is better control through the use of the fingers. Finger grips can vary in shape and size but one very common type of grip used in various patents is the circular grip. One type of circle grip is a sleeve in which the tips of the finger are inserted into the sleeve. The circle sleeve grips are attached at the end of tweezers. Circular ring grips are similar to the circular sleeve where the tip of the finger is inserted into the ring structure. Ring grips are attached directly to one or more blades of the forceps along the length of the blade instead at the end of the blade. When using these forceps one finger is directly inserted into each circular ring grip. These grips allow the user a greater amount of control while also ensuring the fingers do not lose contact with the forceps. In some cases these circular grips are also used to lock the forceps into an intermediate position between the fully closed and fully open position. This allows the user to manipulate tissue of various thicknesses while possibly avoiding damage to the tissue by over exertion from the user creating forces that may be dangerous to the tissue. (Luh, 2010; Ran Oren, 2008; Smith, 1966; Treat, 2006)

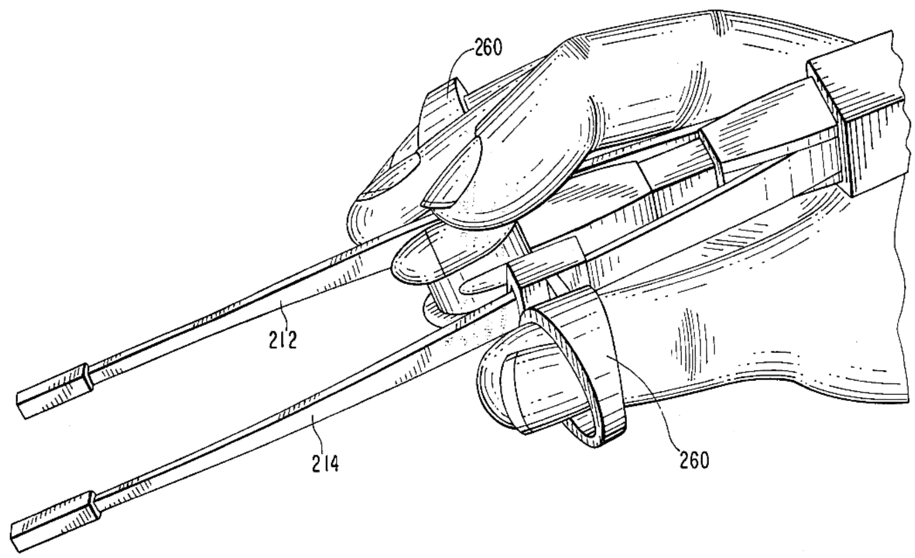


Figure 7: Ringed Forceps (Treat, 2006)

Handles are different from grips in that more than the finger is used as a point of contact and control. Handles for forceps typically are placed over the entire forceps acting as a sleeve or are built into the forceps structure. These handles can be held in various fashions including but not excluding the “pencil-grip” and “Vardon golf grip.” Regardless of grip, these sleeves are meant to give greater feel and control. As seen in figure seven, this handle is different from others in that it allows for direct linear force from the hand to articulated arm with precision and accuracy.

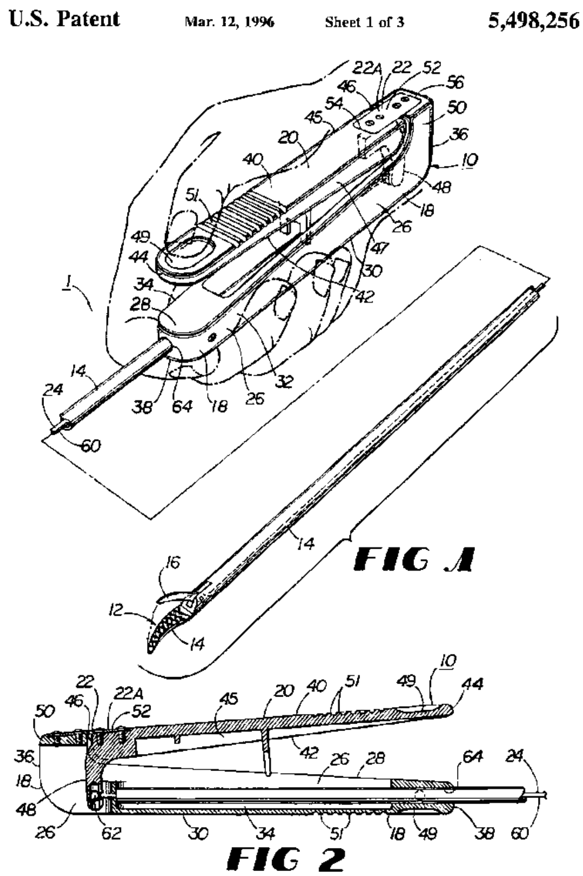


Figure 8: Surgical Instrument Handle (Furnish, 1996)

Handles also help the user to have a proper, controlled grip and handling of forceps. This forces the user, with the use of a sleeve or apparatus, to properly hold forceps and also limit hand movement in specific directions and orientations. Some handles are designed with a rounded contact area on the arm of the forceps. This design claims to give better handle orientation and is rotatable in one orientation. (Furnish, 1996; Nallakrishnan, 2012; Salai, 1991; Tillim, 2005)

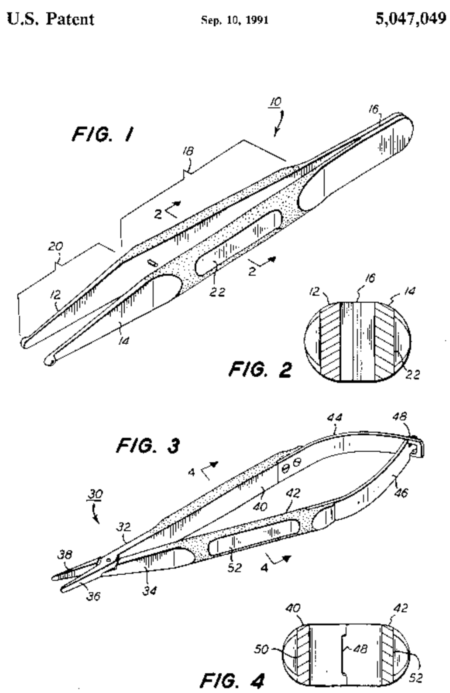


Figure 9: Self Orienting Instrument Handle (Salai, 1991)

3.0 Project Strategy

In order for our team to properly complete the project, a plan for all the steps of the design process was determined before moving forward. The project started with the initial client statement, followed by the steps of the design process and ended with conclusions of future work to be done.

3.1 Initial Client Statement

Using material selection and manufacturing techniques explore the opportunities to innovate a new design of forceps. Classify parameters of mechanical properties focusing on force, weight and movement. Prototype forceps design to facilitate ease of use through ergonomics.

3.2 Objectives

After discussing the goals of our project with both of our advisors we decided that ergonomics, standardized design, cost effective, and safe were the four main objectives. Pairwise comparison charts (PCC) were completed for objectives and sub-objectives and can be found in appendix B.

Ergonomics**-** The most imperative part of our project is to increase the comfort and ease of use for surgical tools, specifically tissue forceps, through the use of ergonomic design improvements. This includes measurements and analysis of weight balance, grip location, and mobility of the tool in the surgeon's hand during use.

Standardized set of forceps- Due to the number of different specialized types of forceps used for varying applications, our group will aim to use design concepts that can be applied to many types of forceps without impeding their function.

Cost efficient- There is a need to make this design cost effective for a hospital to use in procedures. If this pair of forceps is going to be of disposable materials then it must be sterilized and packaged. If they are intended to be non-disposable then they need to be durable enough to withstand autoclave cleaning. Both of these considerations come into play when aiming to make a pair of forceps that are cost effective.

Safety- In using a pair of tissue forceps during surgery there is generally a very low potential for the tool itself to present any safety hazards to the surgeon or the patient. With that being said, we want to make sure our group's design is consistent with standards for safety within the surgical room environment.

3.3 Constraints

Withstands sterilization process or one-time use- Any surgical tool to be used in an operating room must comply with sterilization standards. Whether it be sterile packaged, intended for one time use, or autoclaving, for repeated use, it must be a durable tool.

Non-limiting mechanics - The device must not limit a surgeon by impeding him/her from using the tool for its basic functions. This includes grasping tissue and rotation, movement and extension of the tool in the surgeon's hand.

Size: The forceps must be scaled to fit in the average hand, as defined by the team, to facilitate ease of use for any hand size. .

Biocompatible- The tissue forceps that our group designs must be made of a material that will not elicit an inflammatory or otherwise negative reaction from the body.

Thumb-finger forceps- The type of forceps that we are using fall into the category of thumb and finger, which means that only the index finger and thumb are used to grip and pinch the forceps. An example of this type of tissue forceps can be seen in figure 4, in the patents section of this paper.

3.4 Revised Client Statement

Design, create, and test prototypes of forceps primarily for the use of tissue manipulation. The design should incorporate themes of ergonomics including length, width and mobility. The design will need to increase the comfort, control, and stability the surgeon has when using the tissue forceps, by limiting the amount of movement of the wrist and shoulder. Ratios will be used to standardize design of multiple types of tissue forceps to fit the hand of surgeons with varying hand sizes. Materials must be biocompatible, disposable or non-disposable sterilizable in order to control costs. All these factors must be safe for both the patient and user.

3.5 Project Approach

Using the objectives and constraints of our design, our group has established functions and specifications for the final design of our device. A function-means tree will be created to help identify all of the means through which the functions will be performed. After this we will be generating a group of design alternatives that satisfies our expectations and fall within the scope of our project. These alternatives will be evaluated and the best one will be chosen. After selection of the best design has occurred, we will put together a list of plausible materials that can be used for fabrication. These materials will be fit for sterilization and be relatively inexpensive as compared to other products currently on the market.

An important part of the design process for this project will be to evaluate and test our designs. This will be done with a variety of computer modeling and empirical testing. SolidWorks and CAD software will be used to model our design alternatives and evaluate their physical features. In addition, Finite Element

Analysis (FEA) will be used to calculate the distributions of forces and stresses on SolidWorks models . This will allow us to make assessments of the concepts of design that we are using. As we select and create prototypes from our design alternatives, we will look to gain the help of other surgeons in testing and evaluation of tissue forceps. They will have the opportunity to actually hold a prototype and perform a task that requires precise movement and accuracy. They will give us feedback about the forceps design that will be both qualitative and quantitative.

Pairwise comparison charts that were completed by Dr. Dunn give us a good idea of the importance of different objectives and sub-objectives relative to one another. This will aid the group in giving us a documented source of input from our client and help make our goals for design alternatives clear

3.6 Testing Protocols

Multiple types of testing were performed for our project. Preliminary tests were done on swine to reenact the movement and uses of forceps in surgery. Client testing was done throughout the project, surgeons were contacted and they were able to handle the design alternative forceps in which they stated aspects that were better than conventional forceps and areas for further improvement. Final prototype testing was done with the use of an “obstacle course” and swine testing to finalize the prototype and compare to conventional forceps.

3.6.1 Preliminary Swine Testing

The first test was done to determine force while manipulating the skin of the swine. Force was determined to be the main quantifiable testing protocol for the team because one the main characteristic of a forceps is to manipulate tissue through the use of a compression force. Swine was chosen as animal model because of the similar anatomical properties to human tissue. Swine models were cut with a straight incision using a scalpel. Using Instron testing on the forceps, force was calculated to determine the force needed to manipulate the tool and close them. The initial calculations were used as the standard for the rest of the project. All prototype testing was modeled and changed based on the results found from preliminary testing.

3.6.2 Surgeon Testing

Testing with our client was done using rapid prototypes. We rapid prototype many of our SolidWorks models and gave them to our client in order to test for ergonomics. He commented on the rotational movement of the sleeve as well as the length, diameter and area of surface for the gripping area. Through this feedback we were able to modify our designs.

3.6.3 Final Prototype Testing

The final prototype was tested in two fashions. The first design was tested using a rotational test. In this test we compared the rotational capability of the control group of steel forceps. Our other group for comparison was done with our final design. The second way we tested our final design was with our client using porcine tissue. Our client commented on the mechanical properties as well as the ergonomics of our design. At the end of testing both modifications and future recommendations were made to better achieve the overall project goal.

4.0 Design Alternatives

4.1 Needs Analysis

After our first few meetings with our client, the project was narrowed down to feasible goals and objectives. The client asked for an ergonomic forceps, that is better functionally and more comfortable than forceps currently on the market. It was also decided, by the client and team, that the focus of the project would only deal with the handle portion of the forceps. Knowing this fundamental information our team devised our first pairwise comparison chart in order to understand the most important aspects of our project.

Four main objectives were established by the team after the first set of meetings with our client. After the completion of a pairwise comparison chart by our client, Dr. Dunn (Appendix B) our four main objectives were ranked in order from most important to least important. Ergonomics was the most important followed by cost and standardized set of forceps. The least important was safety. Even though safety was ranked the least important, all designs needed to be safe for the user and patient in order to pass FDA safety regulations and ultimately be ready for the marketplace.

Based on the fact that ergonomics was the most important objective, and because it included many aspects, we developed a second pairwise comparison chart for just ergonomics. This second pairwise comparison chart was completed by Dr. Dunn (Appendix B). The most important objectives ranked by Dr. Dunn were rotational movement, force applied, center of balance and grip location. As a team, we decided that the objectives concerned with ergonomics were the most important for the project in terms of design aspects, and that the other main objectives were more associated with material choice.

4.2 Functions and Specifications

Based off of our ranked objectives we devised a list of important functions and features. Due to the nature of our project, functions included features to the design as well. In a group meeting we brainstormed a list of means in order to successfully implement each function and feature of our design. To organize our ideas, the functions/features and their means were broken down into a Function-Means Chart. This chart helped our team formulate initial design alternatives.

4.2.1 Functions/Features

Our device needed to do one major task during surgical procedures, and that is to grasp and manipulate tissue in a variety of orientations. Based off of this main function, the device must allow the surgeon to maintain constant and sufficient force applied to the tissue by the forceps' teeth throughout a surgical maneuver. To achieve this function, the forceps require a feature to allow and demonstrate rotational movement stability. The features of our device include handle material, grip shape, grip style, and the attachment method of our handle. The functional requirements are mainly focused on the rotational movement and proper elastic return of the device morphology.

4.2.2 Specifications

There currently is not a standard for the length, width, shape and weight of surgical tissue forceps. In order for our device to achieve its main objective of being ergonomic, we determined, through background research, some ranges for these parameters and other specifications of our device. To match the current weight of tissue forceps, which surgeons have been so accustomed to, it was determined that the device be between 125-140 mm in length (Robinson & Lyon, 1994). Studies have shown that the precision at which the surgeon operates under, specifically the amount of force applied by the forceps, can be in a range from 0.5-8 N of force (Dalvand, Mohsen Moradi, Bijan, Saeid, & Fatemeh, 2013). There are different tissues in the body so the forceps will need to use different amounts of force on these tissues without local trauma.. Our device must be able to tolerate up to this amount of force while maintaining a control.

4.2.3 Functions and Means

In order to determine the means in which our device will achieve and demonstrate the functions and features our team put together a Function-Means Chart in table one.

Table 1: Function - Means Chart

Features/ Functions	**Means**				
Attachment	Welded	Slide-On	Snap on	Sleeve	X
Elastically Return	Material Selection	Friction mechanism	X	X	X
Grip/ Reduce Slipping	No grip	Ring	Indented	Hole	High-Friction Surface
Grip Shape	Circular	Rectangular	Elliptical	Lines	X
Handle Material	Metal	Polymer	Mixture	Wood	X
Rotational Movement	Shape	Pivoting Point	Multi- Prong	Pivoting Head	X

Means for the attaching the handle of the forceps include either a welded attachment, a slide-on, a snap-on with clips, or a sleeve style attachment. A welded attachment for our device would mean that our material choice is limited to metals and alloys, and that our attachment would be non- removable/ fixed. The slide on attachment would have a small cavity for the forceps to fit into and would be a removable addition to the common spring steel design. The snap on would be similar to the slide on without the cavity and with teeth that clip onto the steel forceps edges, possibly through the use of an adhesive. The sleeve would simply be a tube like structure that would be pulled over the outside of the forceps, requiring it to have some elastic properties. Issues with attachment include sterilization and wear resistance over time. The elastic return of the device depends on the material selection or the friction mechanism allowing return. Material selection is considered because materials like spring steel demonstrate elastic bending properties ideal for surgical instruments and is easily autoclaved.

To grip the forceps and eventually tissue, the forceps demand a means of gripping though either no grip, a ring-like finger insert, and indented grip, a holed surface, or a high-friction surface. The ring grip consists of a ring attached to each side of the forceps to increase stability in the surgeon's hand. An indented grip would have a small finger shape extrusion cut into the grip to precisely place the finger. The hole-grip and high-friction surface are means of increasing the friction between the surface of the surgeon's glove and forceps. The means in which we will demonstrate grip shape will be; circular, rectangular, or elliptical. A circular grip would mean that if you took a cross-section of the grip location, it would be circular in shape. Rectangular shape would be staying with what's on the market today for spring steel forceps. An elliptical shape is an attempt at combing the idea behind the circular and the rectangular grip shapes. The handle material choice of a surgical instrument led us to the possible means of metal, polymer, or a mixture/composite material. Metal is the most common because of its familiarity and autoclave properties. A polymer or a composite material could also be used as an addition to the spring steel forceps frame as an accessory. Rotational movement of our device will be achieved through its shape, a pivoting point, or multiple prongs. The shape of the design could achieve the rotational function through rounded features allowing a twisting/spinning motion with the fingers rather than the wrist or forearm. Another means of rotational movement could be by using a pivoting point that stabilizes the forceps between the bases of the index finger and thumb and can twist by moving just the fingers. A multi-prong design would allow the surgeon to squeeze a three or a four prong forceps at multiple points around the device to grip tissue.

4.3 Design Alternatives

Design alternatives were created with multiple revisions and reevaluations. In order to not limit the creative design process of our team, team members created the first set of designs individually. Each member presented their design to the team and explained their designs. All designs were focused on rotational movement and or stability. These designs were developed into “mock ups” consisting of tape and plastic in order to give a better visual or 3-D representation to our client. After showing our client our “mock-ups” it was determined that each of the first designs only focused on one aspect of the project. Our team redesigned the first set of design alternatives and included the UMass design in the second set of design alternatives. Once these designs were completed a weighted functions-means chart was used in the selection process for the final design based on our second set of design alternatives.

4.3.1 Design 1: Ringed/ Sleeve Forceps

Variation 1

One variation consists of attaching a circular ring and half circular ring attachment to each of the forceps’ arms. These forceps are held so that the index finger is placed inside the circular ring and the thumb is placed in the half circular ring. The posterior portion of the forceps handle is extended in order to sit on the webbing in between the index finger and thumb. The two finger apparatuses are designed in order to give greater rotational movement, while the extended back handle is designed to provide greater stability when handling the forceps in the hand.

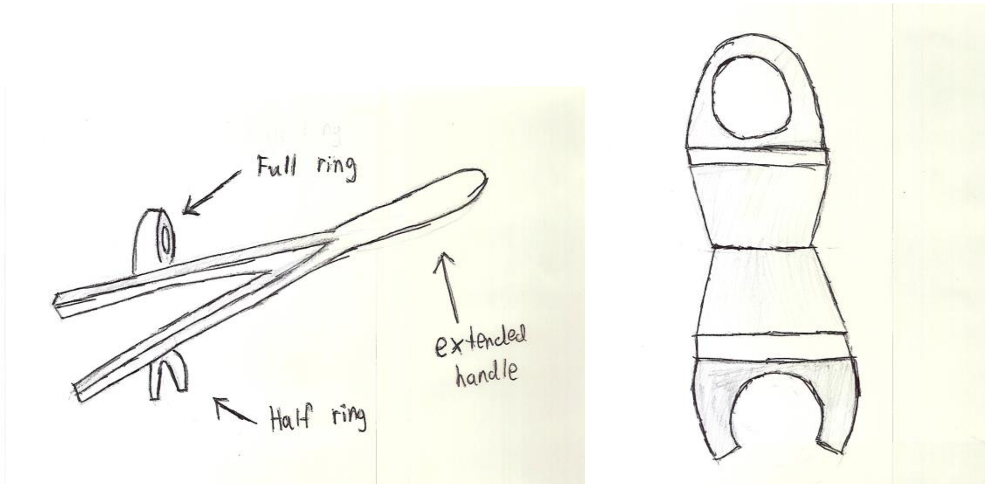


Figure 10: Ringed Forceps Design

Variation 2

In this alternative design, optimization of the control over both the opening and closing of the forceps is the focus. The two arms of the forceps prosthesis remain unmodified from the original design. The upper arm of the forceps is intended for the placement of the index finger supported by the thumb on the opposite, lower arm of the forceps. On this upper arm of the forceps prosthesis, there is a small sleeve designed for the insertion of the tip of the index finger. On the lower arm, there is a slightly larger sleeve for the thumb. This addition to the original design of the ergonomic forceps prosthesis aims to give the user addition control of the grasping function of the forceps. These sleeves are tethered to an attachment point at the apex of its depth, closest to the tip of the forceps. This allows the sleeves to rotate around the tether point and give more degrees of freedom than if it were to be fully secured to the ergonomic prosthetic cover. Not only does this design seek to improve the control over the grasping capabilities of the forceps through the introduction of the index finger and thumb sleeves to the ergonomic forceps prosthetic, but it is also expected to improve the rotational potential of the forceps in the user's hand due to the sleeve maintaining contact with the index finger. The interior surface of the sleeves is hatched with grip lines to improve control.

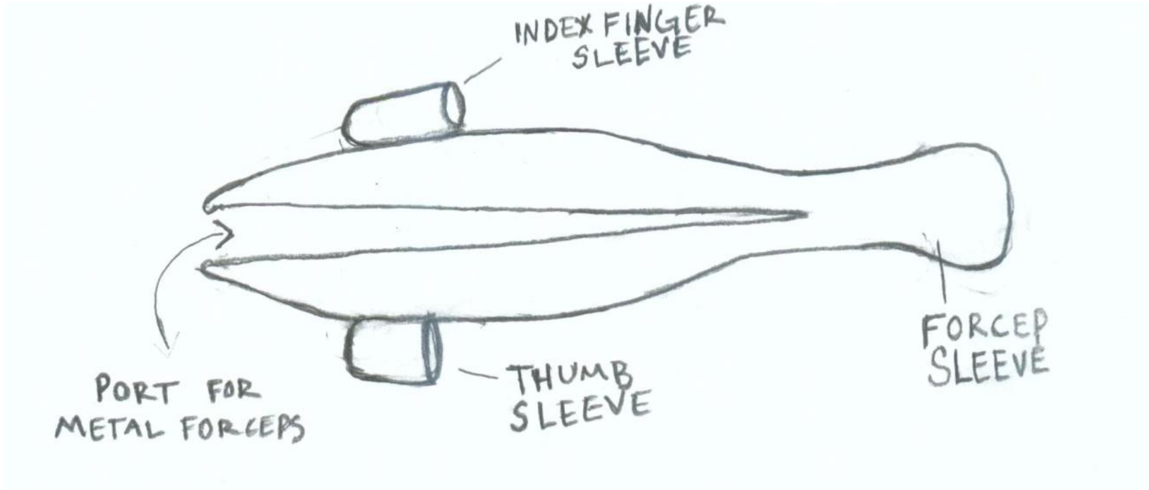


Figure 11: Forceps with sleeves

4.3.2 Design 2: Adjustable Stabilizing Forceps

This design focuses on the resting point on which the forceps lie between the thumb knuckle and the finger knuckle. When forceps are held properly there are three main contact points. These points refer to the thumb, the index finger, and the point between the finger knuckle and thumb knuckle on which the upper portion of the forceps lie. This design involves a semi-circular surface so that the forceps can easily be rotated without the forceps losing contact at this point. To allow for different hand size and different preference, this circular surface will be telescopically adjustable to allow it to hug the hand at all times.

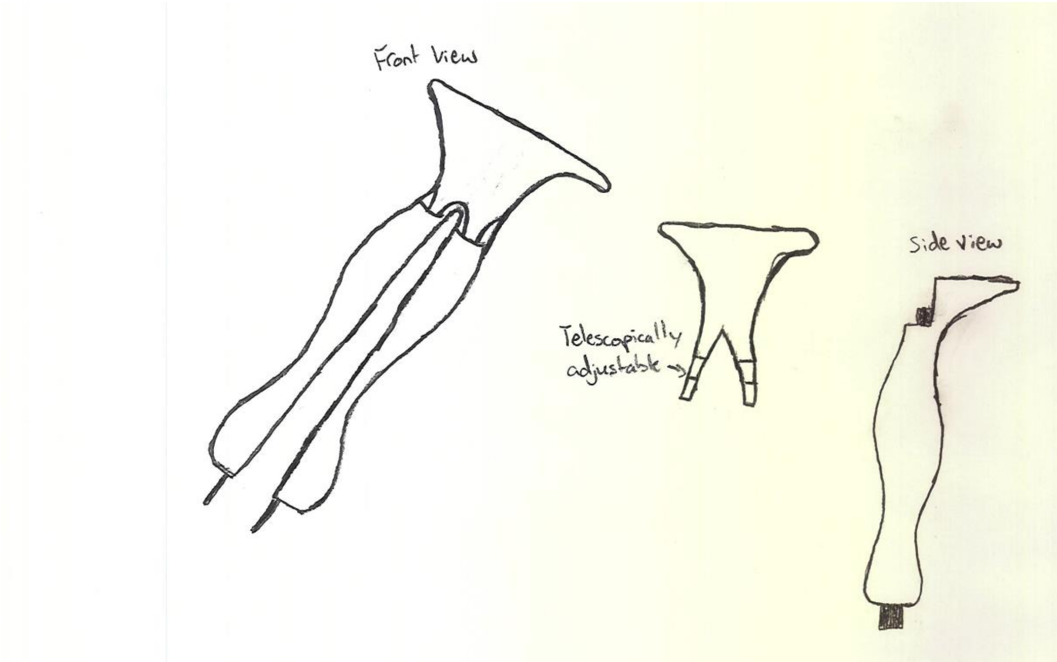


Figure 12: Adjustable Stabilizing Forceps Design

4.3.3 Design 3: Rounded Forceps

My preliminary design focused on achieving the rotational movement function of the device, by improving the ergonomics. Rotational movement was improved by increasing the surface area of the grip by making each surface of the forceps' grip raised up almost semicircle in shape. This allows the surgeon to roll the forceps in just his fingers to pinch or fold tissue in multiple directions without moving the wrist or forearm decreasing precision and increase user fatigue for the surgeon. The grip face is cross-hatched in design. The two points where the forceps contact the hand are at the grip with the thumb and index finger and at the base of those two fingers where it rests. These two points have the largest diameter for more control, around 12-15 mm. The weighting of the cover should not alter that of the spring steel forceps. Material choice would be an autoclavable plastic or composite material as they don't interfere with the weighting or balance issue as much. They are also less expensive and can rapidly be prototyped.

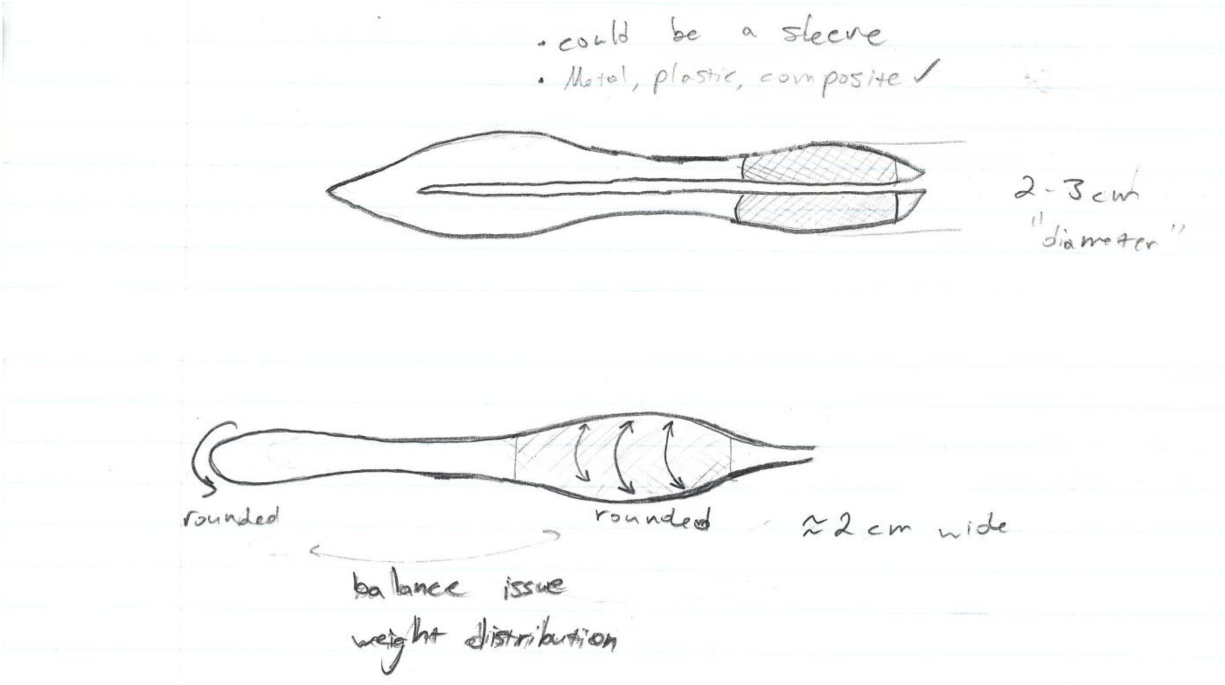


Figure 13: Rounded Forceps Design

4.3.4 UMass Preliminary Design

Dr. Raymond Dunn and the surgeons of the plastic surgery department at the University of Massachusetts Medical School developed some preliminary designs for ergonomic forceps. The preliminary designs are all similar but fall into three main categories relating to how they attach to the forceps. One design is the use of a sleeve in which the forceps are inserted into the sleeve; this is seen in figure 13. The second design is where two parts snap on to the forceps blades. The final design is a whole body forceps where the design is integrated into the forceps and is all one material. These designs all have half-circular rounded beams with a textured grip. The proximal end of the forceps is also circular and rests on the webbed area of the hand between the thumb and finger, in order to give better support for the surgeon using it. This design is intended to increase rotational movement with the use of the fingers, while limiting wrist and arm movement. This preliminary design is the starting point of our project. Our team intends to use this design as a foundation to develop a more ergonomic forceps.

Figure 14: UMass Preliminary Design

4.4 Conceptual Design

The ergonomic tissue forceps prosthesis is intended to allow a surgeon to have the most optimized and unlimited access to the degrees of movement that are require for surgical procedures. When manipulating tissue with thumb and finger forceps, rotational capability is limited by the design of a typical surgical stainless steel forceps. As shown in figure 14, the flat arms of the forceps along with the flat gripping portion does not allow for the most favorable rotation or extension of the tool in the hand.

Figure 15: Traditional forceps (www.medline.com)

The modifications made to improve the prosthesis for tissue forceps improves rotational capability of the tool while limiting the interference with its function of grasping tissue during surgeries. The body of the forceps, shown in figure 13, is cylindrical in its design and is composed of two arms extending from the top of the prosthesis. The arms that extend downward toward the tip of the forceps are round on the top of the gripping portion in order to increase the amount of surface area contact with the fingers, and maintain this contact while moving the tool in the hand to increase the control over the instrument. The bulbous end just above the gripping portion of the prosthesis balances the tool and the prosthesis in the hand and also acts as an additional point of contact for the portion of the hand in between the index finger and thumb. This part of the design will roll over the web in between the thumb and index finger and imparts more stability over the apparatus. On the interior surface of the device, there is a rectangular insertion port in between the two arms of the forceps prosthesis for the placement of the apex point of a pair of forceps. This is the anchoring point for the forceps to be attached to when the ergonomic prosthetic sleeve is slipped over a pair of forceps. The anchoring point will stabilize the forceps within the prosthetic sleeve and allow the apparatus to be used correctly without corrupting its normal function or uses. The prosthesis would be appropriately sized for different forceps so that all would fit and be used easily as instrument in surgeries would. In addition to its ergonomic features and its ability fit to different types of forceps, the redesigned forceps have a standard tip design that is flat, allowing the end of the steel forceps to protrude out the end of the sleeve. Tip specialization for different types of surgical procedures is maintained and will not be removed due to the orientation of the sleeve and the way it fits over the tool.

By using the ergonomic tissue forceps prosthesis, a surgeon will have much more fitted and comfortable tool to work with which will impart better precision and accuracy in surgeries that require careful manipulation of sensitive tissue. It is hypothesized that this increase in the practicality of tool use on surgeries will result in better recovery times, quicker surgical procedures, and less complications overall.

4.5 Feasibility Study

To determine and assess the practicality of the ergonomic forceps sleeve, multiple preliminary tests were done with more qualitative results as opposed to quantitative results. To determine the dimensions of the sleeve, multiple tests were done to attain the highest possible comfort level and also improving the functionality of the forceps.

4.5.1 Design calculations

The computer automated designs were analyzed using force analysis. This was to ensure that the forceps were capable of being used by surgeons of different grip strength. We compared this with the average forces that the human hand exerts when using the tip pinching grip which is the same manner in which medical professionals grip forceps.

Figure 16: Tip pinch force being exerted on a quarter

To allow for our design to meet the needs of any medical professional we used the average data performed in a study of both males and females. This study used both dominant hand and non-dominant handed tests to allow for any difference of hand strength. The results are shown in the table below (Ugurlu & Özdogan, 2012).

Table 2: Tip force table (Ugurlu & Özdogan, 2012)

	Male	Female
Dominant	108	78
Non-Dominant	103	74

Research shows that in order to avoid chronic pains and stresses in the hand the maximum force that can be exerted by the user on a precision tool should be below ten percent the users maximum pinch force(Corlett, Wilson, & CORLETT, 1995). Using this research and the lowest value for the maximum pinch force we calculated that our device must be able to complete its functions when only 7.4 N are applied to the grip area.

4.5.2 Dimension Testing

In order to achieve the most comfort in handling these modified forceps we intend to design, we created a list of dimensions of which we can create the most comfortable forceps sleeve. To gain feedback on the physical specifications of our design we decided to test length, diameter, grip location and grip surface. To test these we created multiple prototypes, using a 3D printer, each with varying dimensions so that we could get feedback on comfort level and ease of movement from various surgeons.

To limit the variables of the testing we decided to test one physical specification at a time, the first being length. To start we created prototypes with different lengths but all containing the same diameter, grip location and grip surface. After measuring the set of forceps we were creating the sleeve for we decided to would be between 100-150 mm in length.

Using the information gained from the surgeon feedback on the desired length of the forceps sleeve we focused on the diameter of the sleeve. To do this we created prototypes with varying diameters, with all of the prototypes being the desired length from the previous study and also with the same grip surface and grip location.

After gaining feedback on the desired diameter size we then knew the length and diameter that would work best for our design. We then created more prototypes with the set length and diameter with different grip locations and with grips that covered different amounts of surface area. However we kept all of the grip types, or grip surfaces, the same so that in this study we could specifically focus on just the grip location before we started testing for possible grip types. After getting feedback on the grip location all we had left for the physical specifications of our design was the grip type. We came up with four different grip types to test, being diamond shaped surface extrusions, simple circle extrusions, straight line cuts, and a gel-like material that could be easily sterilized.

4.6 Preliminary Data

The following tests were done to analyze the functionality of our design. The focus of this testing was on the ability of the forceps to grasp and manipulate tissue as well as the rotational ability of the design.

4.6.1 Rotational Data

To test the rotational ability of the design we used video analysis. We used samples of pig skin to construct this test. The surgeons were told to cut a slit of the top layer of skin in a U-shape and separate it from the layer of tissue below it. This would allow the surgeons to grasp the tissue and allow them to use a rotational movement to flip the tissue over. The surgeons were asked to keep their wrist in contact with the surgical table, mimicking the most stable and precise action made during a surgical procedure. A reference line was drawn onto their wrist to allow for a point to be measured through video analysis. The surgeons then conducted the flipping motion using standard forceps and then again using our design. Video analysis was used to measure the angle of change of the reference point when this motion was performed with both the standard forceps and the design. These videos were compared to validate that manipulating the tissue in the same way, using a rotational motion, resulted in less wrist movement in the design as opposed to the standard forceps.

4.6.2 Applied Force Data

To test the forceps' ability to grasp and manipulate tissue we needed to make sure that the sleeve allowed the forceps to create enough force to allow for the grasping of various tissues. We also needed to make sure that while performing surgical procedure related movements, that the force would remain constant to avoid the tissue slipping out or the force becoming excessive and possibly damaging the tissue. Using an

Instron compression load cell we tested the force to closure of our sleeve and forceps independently. To ensure the test relates to a surgical procedure we will keep the force between 0.5-8 N pinching force, which is the lowest amount of force to grasp biological tissue (Dalvand et al., 2013).

5.0 Design Verification

5.1 Finite Element Analysis Validation

Validation of finite element analysis (FEA) software was conducted using a constant volume stainless steel 316L (SS 316L) beam with dimensions of 5 mm x 105 mm x 10 mm (width x length x height). We calculated stress in order to compare analytical results with the results from FEA software to ensure it was within a 10% error.

5.1.1 Analytical Model

Using the stainless steel 316L beam we placed four arbitrary forces at distal of where stress was being calculated. The forces used were 5N (f1), 10N (f2), 15N (f3) and 20N (f4). The dimensions of 10 mm (b) x 105 mm (d) x 10 mm (h) were chosen because they were the closest approximations to a single arm of the Adson forceps. Using these dimensions we calculated the moment of inertia using the moment of inertia equation for a square beam.

$$f1 := 5N \qquad f2 := 10N \qquad f3 := 15N \qquad f4 := 20N$$

$$b := 10mm \qquad d := 105mm \qquad h := 10mm$$

$$y := 5mm$$

$$I := \frac{1}{12}\left(h^4\right) = 0.833\, m \cdot mm^3$$

We then calculated the analytical moment in order to calculate the stress for each given force.

$$m1 := d \cdot f1 = 525 \cdot N \cdot mm$$

Using the moment calculation, stress was calculated.

$$stress1 := \frac{(m1 \cdot y)}{I} = 3.15 \cdot MPa$$

The calculated results are found in Table 3.

Table 3: Analytical Calculations

Force(N)	Moment (N*mm)	Stress (MPa)
5.00	5.25E+02	3.15
10.00	1.05E+03	6.30
15.00	1.58E+03	9.45
20.00	2.10E+03	12.6

5.1.2 FEA Model

A SS 316L constant volume beam was constructed in SolidWorks and imported into ANSYS Workbench. A mesh was created on the beam to divide it into individual elements. A fixed support was placed on the surface where the stress was calculated. The force was applied on the distal end from the stress calculations of the beam.

As expected when using this model we found stress to be greatest proximal to the fixed support end and distal to the location of force applied. Due to this factor we did not consider the stress along the length of the beam but the maximum stress which was found at the end nearest to the fixed point.

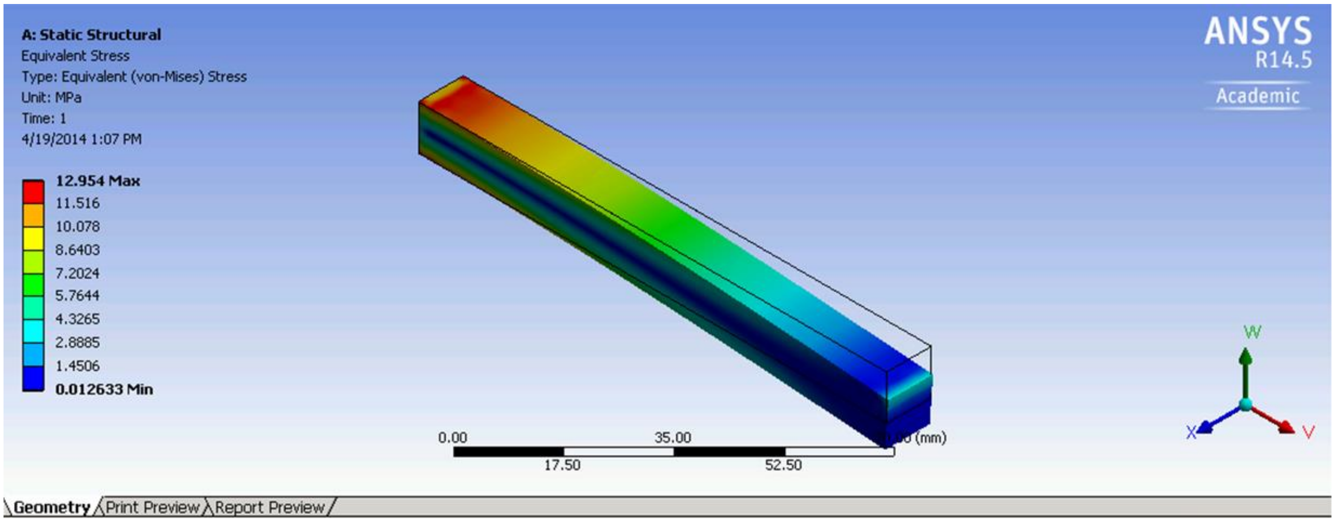


Figure 17: Constant volume SS 316L beam model

This process was completed four times with the same varying forces used in the analytical model. The results were compiled into Table 4.

Table 4: Analytical & FEA results

Force (N)	Stress (MPa) Analytical	Stress (MPa) FEA
5.00	3.15	3.24
10.00	6.30	6.48
15.00	9.45	9.71
20.00	12.6	13.0

As seen in the table the error differences between the analytical and FEA model are relatively small. The average error difference was seen to be less than 3.125% for all forces. Based on these small error differences we concluded that FEA models could be used as means of analysis for our designs.

5.2 Load Cell Compression Test

In order to properly alter our designs we used a 50 N load cell to calculate the compression force to close four different models. The first model was an ABS forceps sleeve that was created by Dr. Dunn and the

UMass Medical team. The second model was a pair of SS Adson forceps. The third model was the ABS forceps sleeve with a pair of Adson forceps placed in the sleeve. The final model used was a PLA forceps sleeve that was created by the team early in the design process. Various forces and the associated displacement were plotted on a displacement force graph.

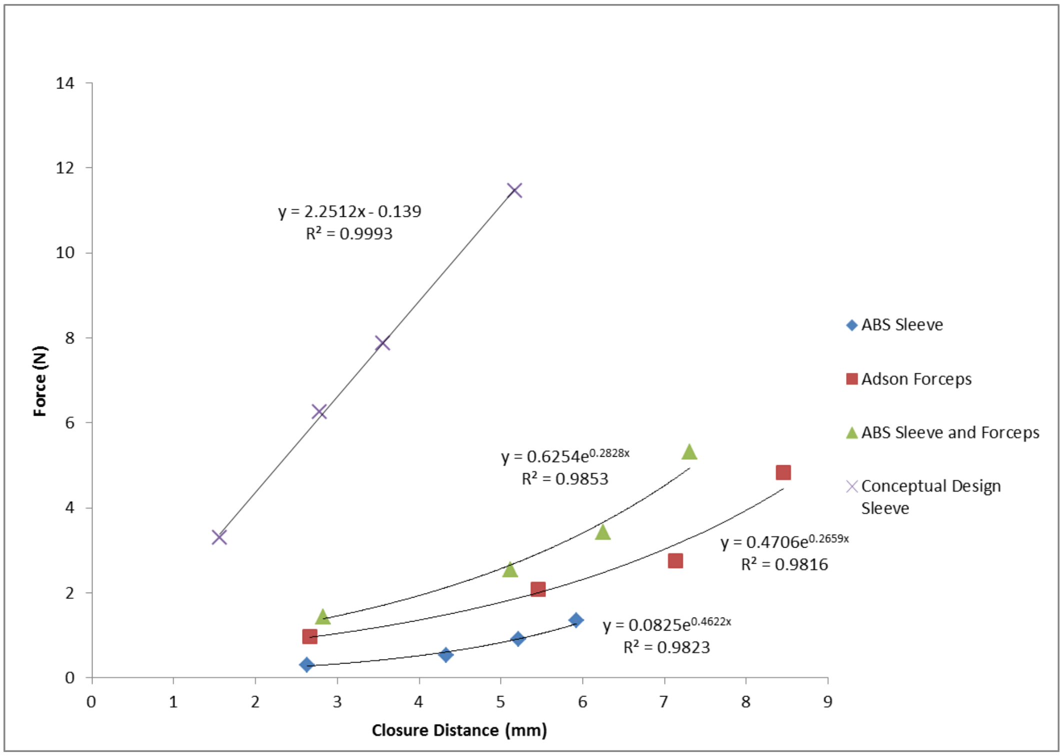


Figure 18: Instron Force Closure Data

From this data we found that the PLA sleeve was our best initial design. Based on this data we decided that we would improve on mechanical properties of PLA sleeve by reducing the force needed for closure while lowering the stress exhibited on the sleeve. By reducing the stress we theorize that with lower stress the sleeve will be less likely to fail with continued usage.

5.3 Design Process

5.3.1 First set of designs

The team decided to create eight different designs with varying lengths (L 1.1-1.4) and varying diameters (D 1.1-1.4). For length the distance from the in-cut to end of the sleeve was changed from 100 mm - 85 mm, while the diameter remained constant. For varying diameters we increased the in cut area for each design, while keeping the length constant. After making these designs we imported each into ANSYS to create FEA models. For each FEA model we created a mesh and chose polypropylene as the material.

Due to the symmetry of forceps and our designs we only applied a compressive force to one side and calculated it to the 3 mm distance which we considered to be the midpoint of our designs. We also calculated the max stress for design. Stress was used to determine if the design would fail reach the fatigue stress of 50 MPa for 1 million cycles(Zhou & Mallick, 2005). Results were compiled into Table 5 for comparison.

Table 5: 1st Set of Design FEA Results

	Closure Distance (mm)	Force (N)	Stress (MPa)
L 1.1	2.95	0.0575	4.24
L 1.2	3.02	0.175	5.66
L 1.3	3.09	0.505	5.53
L 1.4	3.02	0.918	4.32
D 1.1	3.02	0.393	3.39
D 1.2	3.03	1.52	4.72
D 1.3	2.99	4.19	4.72
D 1.4	3.01	7.56	6.76

Based on the results from the table the team chose L 1.1 and L 1.2 to combine with D 1.1 and D 1.2. We chose these because the combination of lowest force and stress was the lowest compared to the others. This was a parameter our team used in evaluating these models on a mechanical basis because we wanted these sleeves to not change the mechanical properties when used with a forceps. This way the surgeon did not have to “recalibrate” their hand when placing the sleeve on the forceps.

5.3.2 Second set of designs

We initially created three designs. The designs were based on taking D series design and changing the in-cut to the L series length. The three design our team designed were L 1.3-D 1.2, L 1.3-D 1.1 and L 1.1-D 1.1. We took these designs and placed them into ANSYS to create FEA models. These models had the same parameters as the first set of designs. Both the deformation and stress values were plotted on graphs compared to the force.

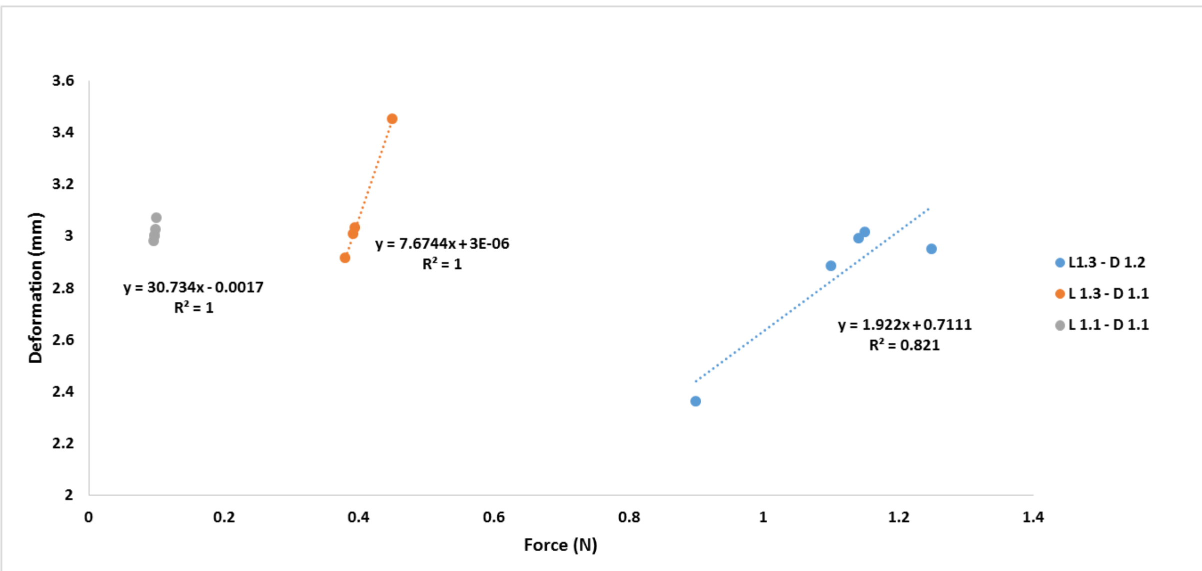


Figure 19: 2nd Set of Designs Force vs. Deformation FEA Results

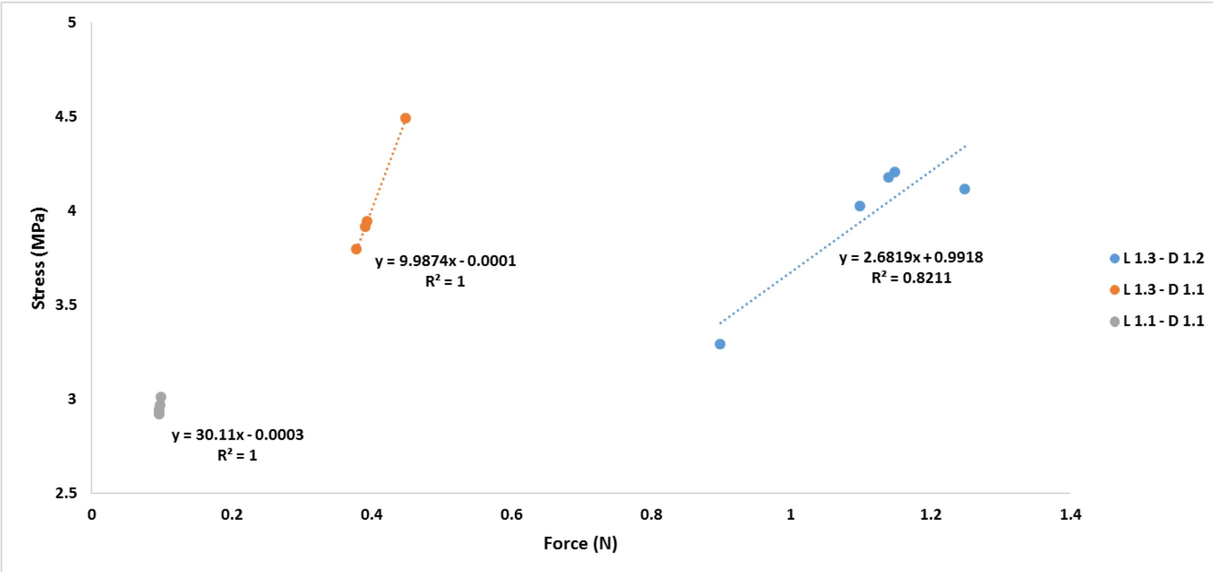


Figure 20: 2nd Set of Designs Force vs. Stress

We used these results to make further design alterations. Design alterations were made to the L 1.3 – D 1.1 and L 1.1 – D 1.1 models.

5.3.3 Third set of designs

For the third set of designs we created modifications L 1.3 – D 1.1 and L 1.1 – D 1.1 which we called L 1.3 – D 1.1 Mod 1 and L 1.1 – D 1.1 Mod 1. We did further FEA analysis with these designs. After FEA analysis we decided to rapid prototype designs L 1.1 – D 1.1, L 1.3 – D 1.1 and L 1.1 – D 1.1 Mod 1. These rapid prototypes were created in order to evaluate the ergonomic function in the hand and for our team to handle the designs we created. Based on the rapid prototypes our team decided to create an additional model that fit the forceps model better than the previous three. Our team saw that with these models that the Adson forceps did not fit properly resulting in slippage and movement of the forceps when handling the models. The design was off of L 1.1 – D 1.1 Mod 1 and therefore we called it L 1.1 – D 1.1 Mod 2. This model had poor mechanical properties but it fit the Adson forceps better. The force required was greater but as a team we felt that the additional force required did not overweigh the fact the previous designs lacked functionality and ergonomics.

5.3.4 Final Set of Designs

The final set of designs incorporated many of the ergonomics that are design required while maintaining proper mechanical properties. These designs were still based off the L 1.1- D 1.1 series and consisted of Mods 3-10. Not all Mods of this series were rapid prototyped but they were all modeled in SolidWorks and analyzed using FEA analysis. In order to maintain proper ergonomics the tool lengths of all designs were between 125 mm and 140 mm, as well as a tool diameter between 5 mm and 12 mm (Robinson & Lyon, 1994). When tool diameter was measured when the sleeve was closed because the tool is functioning when closed, otherwise the tool is only being held. Starting with Mod 3 a grip portion was added and the surface area for the grip portion was increased to give a greater area of contact. This model was rapid prototype to analyze the ergonomic properties.

Figure 21: Final Design Mod 4

As seen in Figure 20 the model was rather bulky and did not maintain the mechanical properties our team desired. However it was the first model that had ergonomic parameters we desired. Using Mod 3 we made changes to the design that altered mechanical properties but had negligible effects on the ergonomics. Changes include reduction in diameter, increase and change in the cut where the two arms are separated as well as other minor changes. All these changes greatly reduce the force need to closure to a range below the 10% maximum force we required (Corlett et al., 1995).

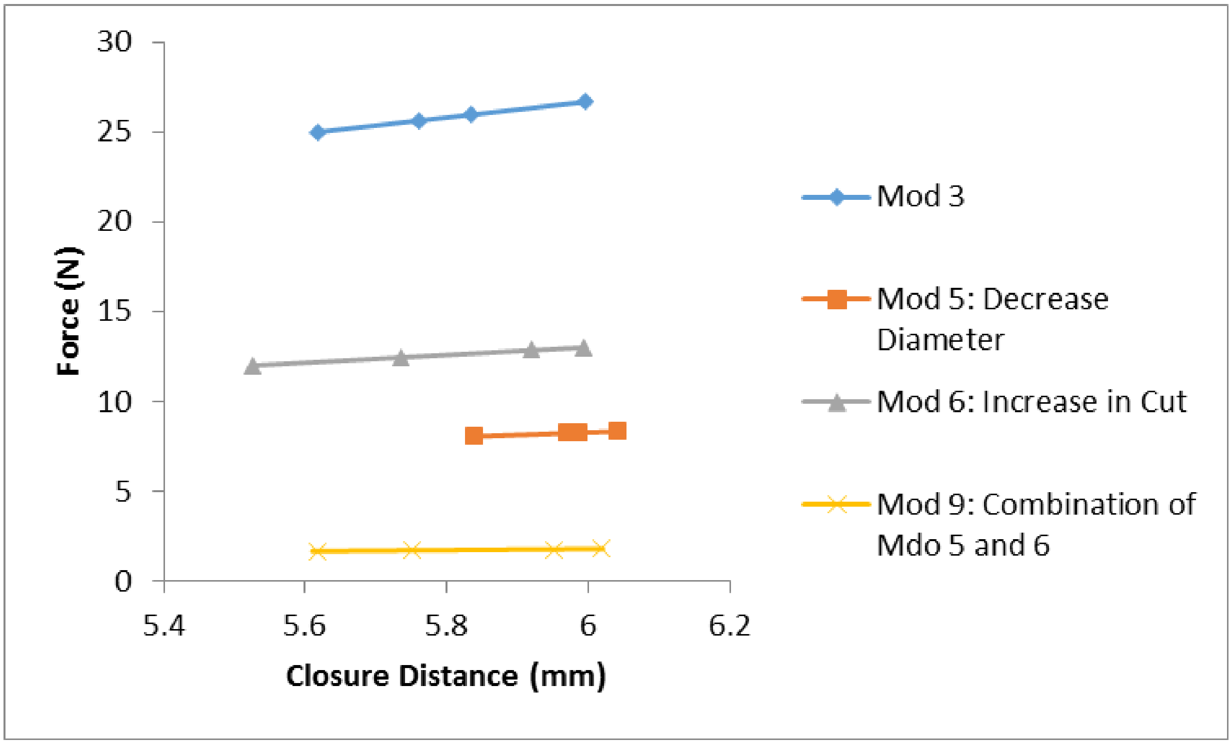


Figure 22: Force vs Closure Distance FEA Results

When analyzing the stress concentration we noticed that not only was the area of stress concentrations reduced but also the maximum stress concentration was less for Mod 9 than Mod 3 for our designs. Even though Mod 3 was below the maximum stress fatigue for one million cycles for polypropylene the reduction in stress gave the team more confidence that the sleeve would not fail for at least one million cycles.

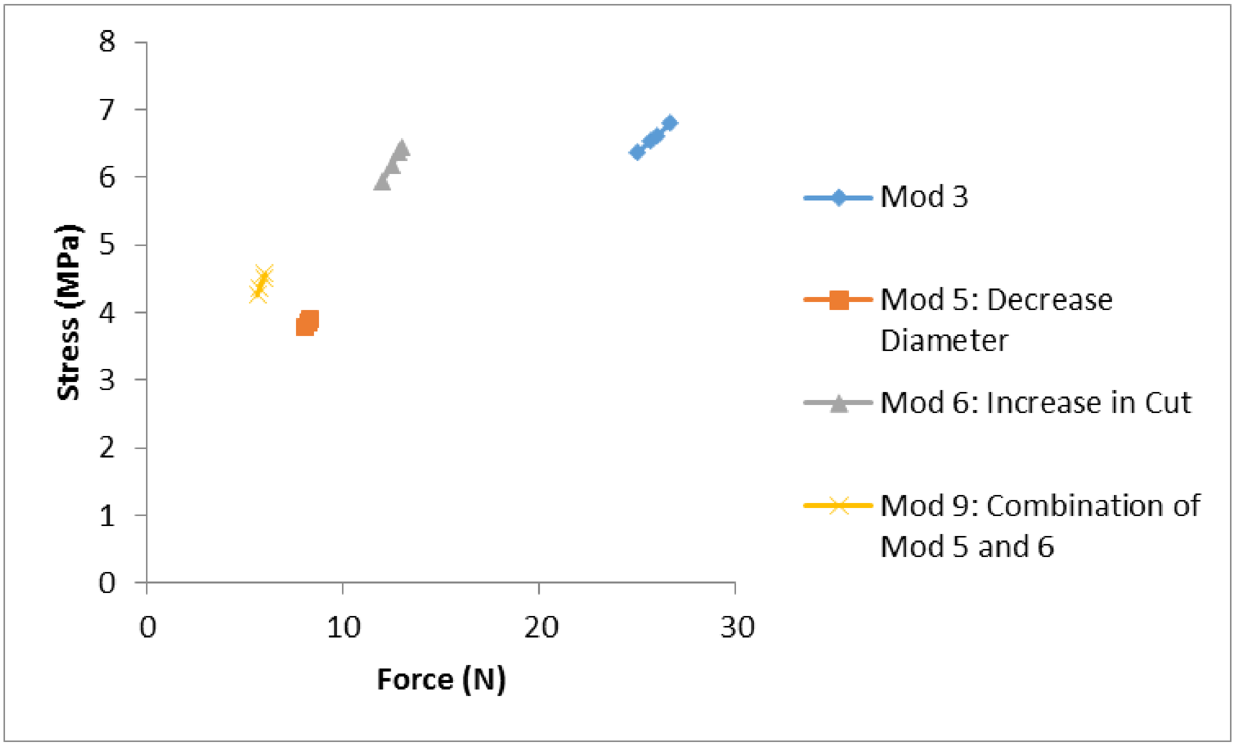


Figure 23: Stress vs Force FEA Results

With the results found in Mod 9 we decided to rapid prototype Mod 9 in order to have Dr. Dunn test the sleeve for ergonomic feel and mechanical properties. When given to our client he said that a slight increase in the curve arch and surface area of the grip portion was needed. Based on these observations from our client we created our last modification for our final design.

6.0 Discussion

6.1 Rapid Prototypes

6.1.1 Initial Rapid Prototypes

Having the ergonomics considerations and some mechanical estimates in mind we created our designs using a computer aided design (CAD) program called SolidWorks 2013. Initially eight models were created in SolidWorks; 4 with varying diameter, and 4 with a varying extruded cut lengths as explained in the previous chapter. Based off of these original eight models and the finite element analysis ran on them we created combinations with the varying widths and the varying cut lengths to make 4 new models. The four rapid prototype designs we came up with were labeled L 1.1-D 1.1, L 1.1-D 1.1 MOD 1, L 1.1-D 1.1 MOD 2, and L 1.3- D 1.1. We 3D printed our four designs using ABS plastic using a company called AshTech Engineering.

When figuring out what shape to make our forceps sleeve, several factors needed to be considered. The design considerations included grip area, balance, overall fit and length/width. When looking at the human hand, specifically the thumb and index finger, we determined, through research support that there was a need for a rounded shape to the grip surface. This was done in order to increase rotational movement of the forceps and to fit the dimensions of the hand better than the bare steel forceps alone. The contoured surface from tip to base was done to match the points on the sleeve where contact with the hand and/or fingers, is made. Each prototype we made makes an attempt to satisfy ergonomics and be mechanically sound. This means that there are neither forces too high required to close the surgical steel forceps with the sleeve on it.

L 1.1 – D 1.1

This model was created base off FEA data gathered on each of the original eight models made. It yielded the lowest force for closure out of all the models. This can be seen clearly when you realize that D1.1 is the thinnest diameter and L1.1 is the longest cut. As you can see in Appendix C this model is thin but has a curved and rounded surface to support ergonomics.

MOD 1

Mod 1 of the L1.1 - D 1.1 was tweaked a little bit from the original by adding some thickness and shape to the base of the forceps and then to the rounded hump, which is right before the finger-thumb grip placement.

L1.3 – D 1.1

This model was made after combining one of the top two L-series sleeves (L1.3) and one of the top two D-Series sleeves (D1.1) This model turned out to be a little thin and over engineered. We weighed the mechanical considerations too heavily compared to the ergonomics. We learned from this model to revert back to our thicker models and go from there in the future.

MOD 2

Mod 2 was another iteration of the L 1.1 – D 1.1 with more thickness added to the area where the cut ends in the material, with strictly ergonomics in mind. This area is prone to the most stresses and therefore needs to remain thinner to maintain minimal stresses. We decided to add a small amount of thickness to this area and sacrifice some already satisfactory mechanics for more ergonomic appeal. Handle and grip area thickness was added because it was determined that adding material to these areas will not affect mechanical properties. The closure force was slightly affected due to added thickness at the cut's end, but the ergonomics were most satisfactory to our client. This model was the closest to what our client envisioned our final design being so we continued to alter the ergonomics inside more realistic mechanical bounds.

MOD 3-9

Mods 3 through 9 had the greatest focus on ergonomics and mechanical properties. Instead of making and rapid prototyping all the designs the team decided to use FEA to create a model with proper mechanical and ergonomics before creating a rapid prototype for our client. Through many iterations and analysis in FEA Mod 9 was developed with the best possible mechanical properties while minimally changing the ergonomic properties.

6.2 Environmental, Societal and Ethical Concerns

6.2.1 Environmental Concerns

The use of our device will be mainly focused in hospital operating rooms as well as other health care capacities, aside from testing that may take place in a laboratory setting. For this reason the impact of our project on the natural environment will be minimal (Hamskog, Klügel, Forsström, Terselius, & Gijsman, 2006). The plastic product being used, varying grades of polypropylene, are recyclable and may be discarded after it has been replaced or fulfilled its purpose.

6.2.2 Societal Concerns

One of the goals of designing an ergonomic sleeve for tissue forceps is to make it a universally fitting concept for the many different types of tissue forceps that vary by length, width, tip type, grip etc. This is accomplished through a balance of mechanical properties and what we determined as a group to be important ergonomic features. We hope to change the market place for hospital purchases of tissue forceps and make it standard to have a pair(s) of sleeves that can be used on tissue forceps and improve their use as a surgical tool. By increasing the comfort of the tool in a surgeon's hand, we aim to increase the efficiency of the tool and its accuracy in the operating room. By providing surgeons with more ergonomic tools, we aim to increase precision and efficacy of surgeries and thereby benefit society by improving the standard of care. This can include faster surgeries, shortened recovery time, and minimized tissue damage.

6.2.3 Ethics

Ethical concerns for our project are minimal because surgical tools do not draw much controversy in terms of how they perform or how they are produced. Because the polymer(s) being used to create these forceps sleeves are recyclable and not harmful to the environment, the moral principles of the use of our device are not complex.

6.3 Economics & Manufacturability

We have recommended the use of polypropylene as the final material for our forceps sleeve. Polypropylene comes in many different grades and can be copolymerized with other polymers to customize the properties of the material. Because our project is limited to 3-D printing of our prototypes in ABS (acrylonitrile butadiene styrene) it is difficult to determine what type of polypropylene will be used to manufacture a market ready finalized design of our forceps sleeve without further testing. The selection of polypropylene was based on its similarity in mechanical and material properties to ABS as well as its ability to be autoclaved. In addition, polypropylene is relatively cheap, costing $2-3 per kilogram of unprocessed fiber that can be manufactured into the desired form. This along with the price of a metal mold or extrusion die in order to manufacture this product will be the largest cost in the process of getting it to the market place.

The procedures used in this project to produce and evaluate our design alternatives are highly reproducible as they mostly rely on SolidWorks CAD and finite element analysis (FEA) software. The prototypes of forceps sleeves were printed using a PrinterBot 3-D printer with a SolidWorks converted STL file. The testing and validation for our project involved the use of an Instron mechanical testing machine and a camera anchored with a tripod to gather both quantitative and qualitative data respectively.

6.4 Health and Safety Concerns

The polypropylene tissue forceps sleeve will be fully sterilizable by autoclaving procedures and withstand the mechanical demands of repetitive use during surgical procedures. In addition polypropylene is biocompatible in the capacity which we are intending to use it (Konovalova, Nalimov, Zamaleev, & Salakhov, 2013). It will only be used as a sleeve over a pair of surgical steel forceps and its direct contact with living tissue will be limited to the surgical operation it is implemented in. Because its use as a tool is fully controlled by the surgeon and the sterilization practices used at hospitals are very standardized, the health risks posed by our product is not significant.

7.0 Final Design and Validation

The final device design is described in the following chapter including the ergonomic parameters, mechanical properties, and the procedure for using the device in a clinical setting. Along with this, Solid Works CAD models were verified using FEA. Clinical validation is also discussed, specifically our client Dr. Dunn using our device and providing feedback.

7.1 Final Device Design

Through the use of SolidWorks and a 3D printer, we built an initial prototype followed by multiple iterations on the original design. The rapid prototyping process leads us to our final model seen in Figure 19. The device was designed as a sleeve that fits over a traditional steel forceps to increase ergonomics in the handle and grip area, while leaving the specialized steel tip alone. The overall length of the forceps sleeve was 145mm, which is longer than the standard 120 mm Adson steel forceps in order to improve the fit to the hand. In addition, the device needed to have a negligible effect on the mechanical properties of the steel forceps, mainly the closure force. Finally, it was necessary for our device to increase hand/forearm mobility and comfort through improved rotational ability of the rounded surface.

The main features of our design were a sphere-like base (Fig. 19, A), 140 mm in diameter, to maintain proper weight and balance, a slot cut into the base (Fig. 19, B), 3 mm by 6 mm, to secure the steel forceps' base, along with a rounded cut (Fig. 19, C) to minimize closure force while avoiding high stress and low fatigue strength issues. The sleeve also includes a rounded grip surface with a diameter of 16 mm when open including raised bumps (Fig. 1, D) to ensure a comfortable grip. When the sleeve is closed the diameter is approximately 12 mm, within our ergonomic parameters.

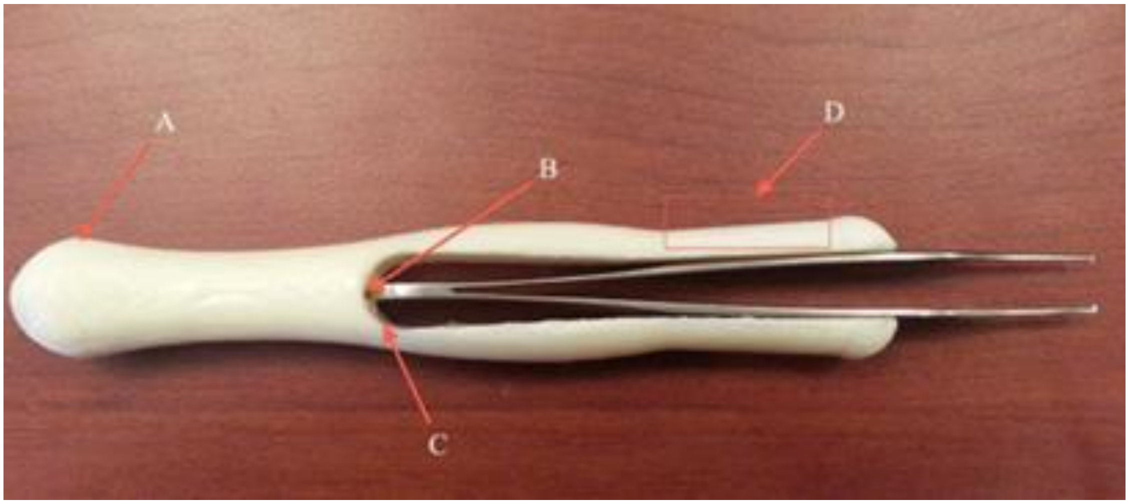


Figure 24: Forceps Sleeve with Dimensions

The sleeve was designed to enhance the ergonomics of the traditional steel forceps by easily sliding it over the steel base and allowing the surgeon to manipulate various human tissues more precisely and efficiently, while alleviating chronic stresses experienced during surgical procedures. The specialized steel tips of the standard forceps were not modified or affected by the sleeve, allowing the surgeon to do specific maneuvers in surgery as before. The key element of our design is the larger, rounded grip surface and handle, permitting the surgeon to rotate the forceps in just using only the index, middle fingers and thumb, rather than an uncomfortable or awkward wrist, forearm, or shoulder position to execute the same precision movement. By decreasing the repetitive stress and strain in a surgeons hand, wrist and forearm during a procedure overall comfort, effectiveness and precision are improved.

7.2 Finite Element Analysis Model

FEA was conducted on the final model to ensure the repetitive stresses experienced during the use of the device would not be too high, leading to fatigue failure in the device. In order to analyze these mechanical properties, our CAD model was opened in Ansys.

A force was applied to one side of the forceps sleeve while the other side was fixed in place. The location of this force was right where the surgeon places his fingertips, in the middle of the grip surface. The force was applied to increase the deformation until the deformation reached 3 mm. This was done to simulate the closure of the forceps tips, which are 6 mm apart. Since one side of the forceps sleeve was being evaluated only 3 mm of deformation was needed to show stresses experienced within the model.

These stresses were examined along the full length of the sleeve. The area of mechanical concern as seen in Figure 20, is located right above where the two arms or sides of the forceps meet the handle and base region.

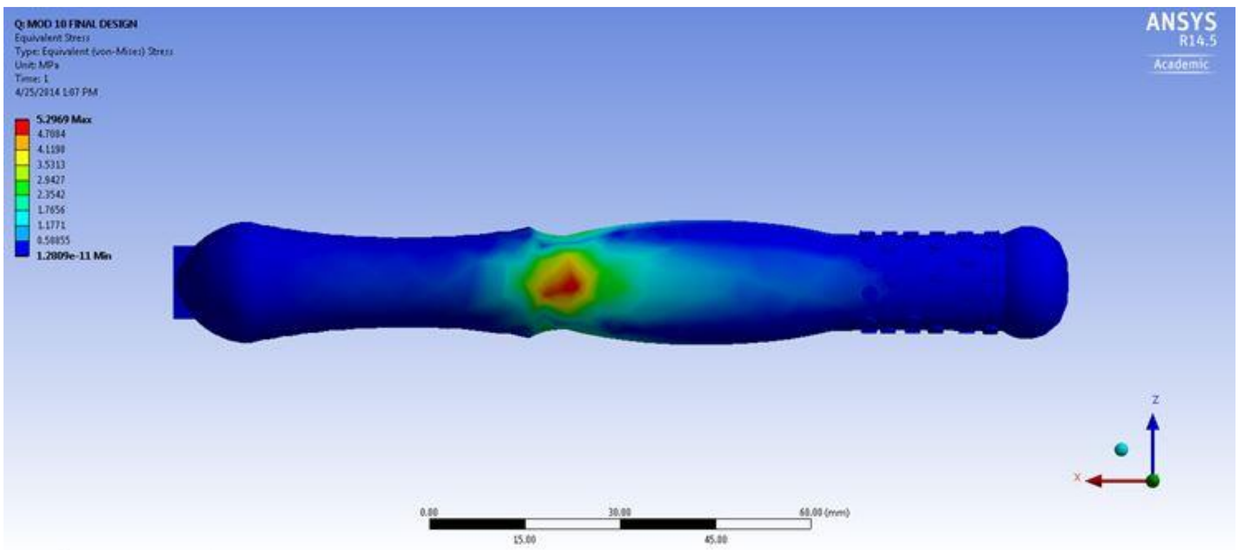


Figure 25: Final Design FEA with Stress Concentrations

The evaluation of these points, where the stress is highest, indicates that less material here leads to less force needed to close. Less material can also lead to a decrease in ergonomics, so a balance between mechanical properties and ergonomics was found in our final model.

7.3 Final Design Force Data

Using FEA and Instron testing we tested our final model to ensure it was below the 10% maximum force parameter we established as mechanically ergonomic to avoid chronic pains and stresses in the hand of the user when our design was used repeatedly (Corlett et al., 1995). We used the Instron machine to calculate the compressive load and closure distance. Due to the fact that our model dealt with small distances and there was the possibility of the two load cells of the Instron machine coming in contact we decided to manually move the load cell of the Instron machine. We recorded both the force and distance at six different positions. These were then plotted and a line of best fit was applied to the data. We used the force data from FEA and also plotted them as seen in Figure 22.

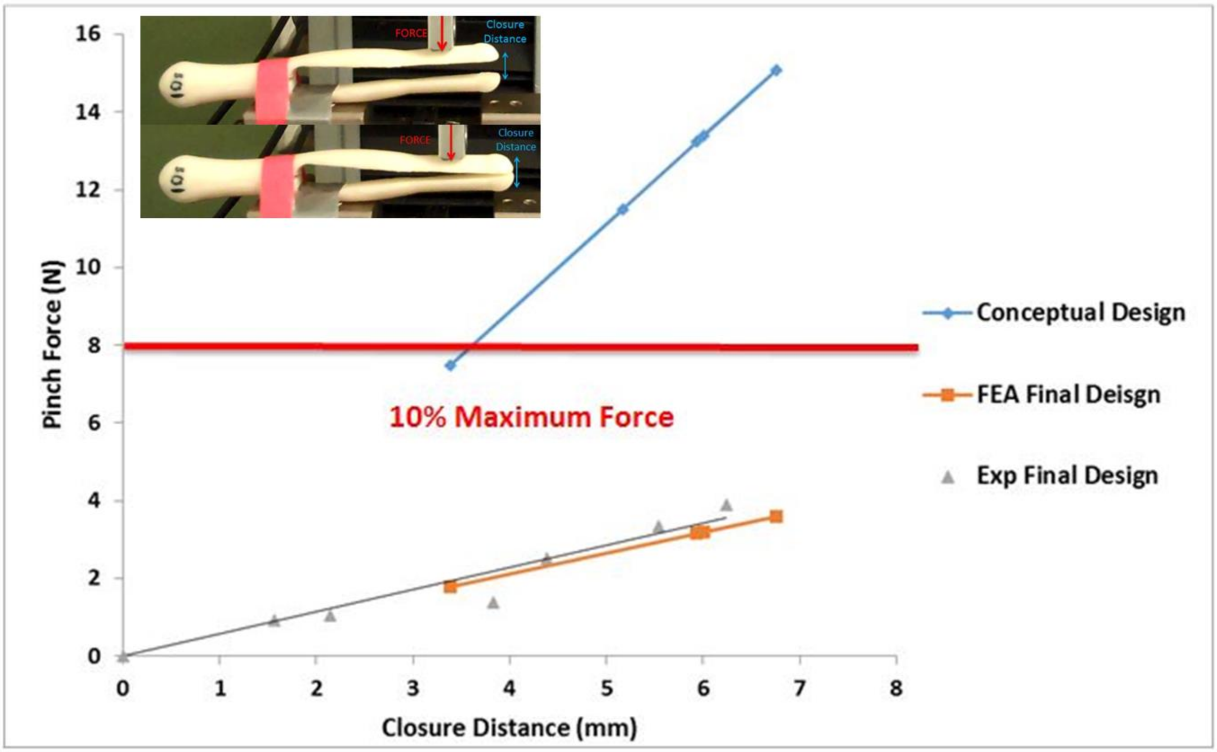


Figure 26: FEA and Instron Force Testing

Both the force data from the FEA and Instron machine were below the 10% maximum force, which could possibly alleviate chronic stresses and pain. As seen in Figure 22 the FEA and Instron data were very similar this further validated the use of FEA and ABS plastic for our rapid prototypes. This graph also shows how our team's final design was mechanically superior to our conceptual design.

7.4 Rotational Testing

In order to test for improvement in ergonomic rotational movement we took videos using the final design, still images were used from the video to measure rotational degree of motion. When testing a piece of paper was used to act as a piece of tissue. While keeping the wrist and hand on the table we attempted to rotate the piece of paper while retain a constant force. When using steel forceps we were only able to reach approximately 60 degrees before pressure was lost and the piece of paper fell out of the grasp of the forceps. When using the final model sleeve with forceps inserted into the sleeve we were able to comfortably reach 90 degrees.

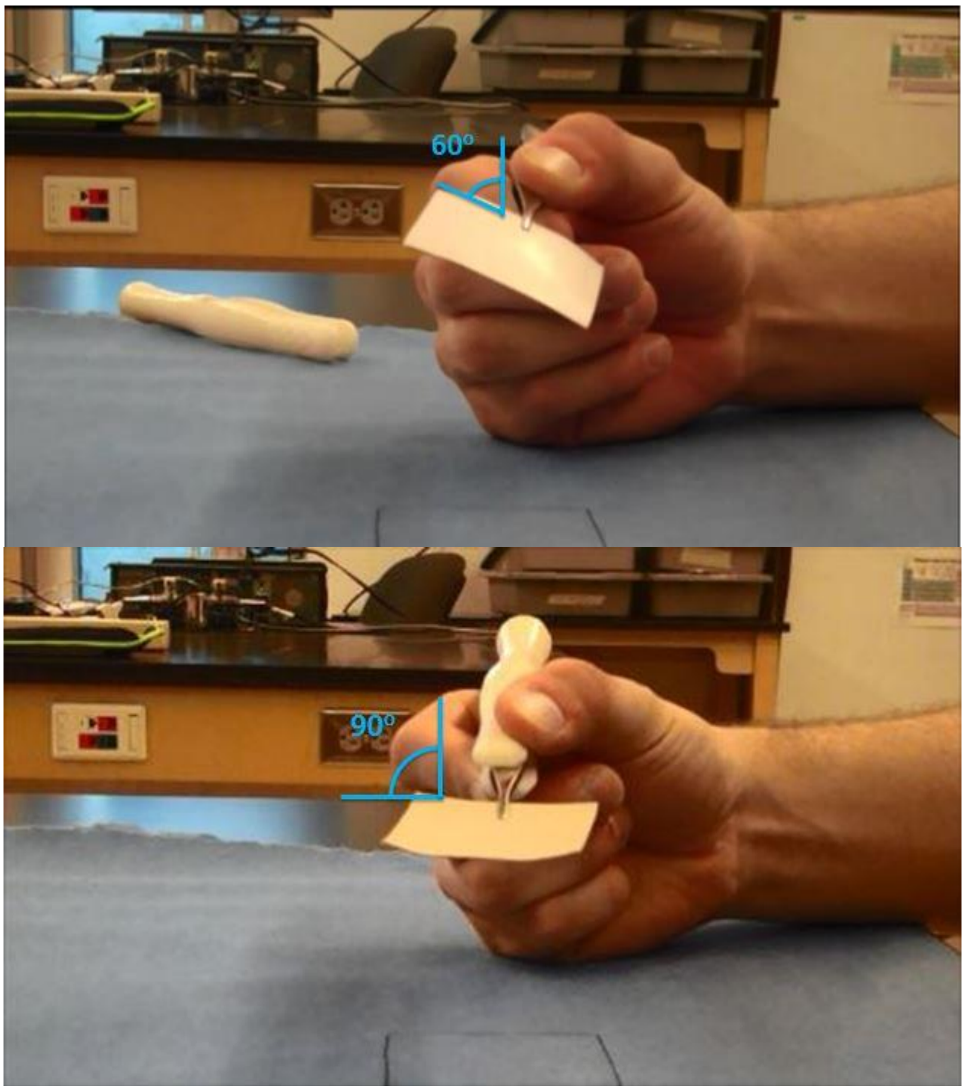


Figure 27: Rotational Testing with Steel Forceps and Sleeve

It was also observed that while using only steel forceps that the user struggled rotating the piece of paper, with several tests resulting in forceps slippage before reaching 60 degrees or the requirement to apply additional force in order to not lose grip on the piece of leather.

7.5 Clinical Validation of Final Design

Our final design could not be autoclaved for use in a human surgery due to lack of hospital protocol pertaining to the sterilization of ABS plastic, but it was used by our client Dr. Dunn in the manipulation of porcine tissue outside of the operating room in a clinical setting a UMass Memorial. Dr. Dunn expressed his satisfaction with the design, as it met all of the requirements he had like the ability to rotate 90 degrees in his fingers comfortably. The design felt right in his hand as our model was made to fit his hand specifically. To validate our design in more than one case (our client) we asked his assistant Oksana Babchenko to provide us with an image of her hand laid flat on a table with a familiar reference point like a quarter to size proportionally. From this image and subsequent hand measurements we created another forceps sleeve to fit her hand. It should be noted her hand is significantly smaller than Dr. Dunn's hand. After allowing Oksana to handle and get a feel for the sleeve in her hand, her feedback was similar to Dr. Dunn, claiming it felt better than just the steel forceps. She also noted the sleeve designed for Dr. Dunn felt better overall than the steel forceps, validating our design and its process.

7.6 Methods for use of Final Design

The forceps sleeve must undergo autoclaving before it is used in a surgical setting, to ensure optimal safety and sterility for the patient in the operating room. The final design was 3D printed using ABS plastic, but for surgery they needed to be produced using polypropylene because of its biocompatible properties. After autoclaving, the sleeve is simply secured by fitting the base of the steel forceps into the slot cut into the base of the sleeve in between the two arms or sides. The forceps sleeve and steel forceps are then used as they normally would be by the surgeon. Some examples of maneuvers made by a surgeon during surgery include suturing a wound closed, grasping, pulling and overall manipulating the tissue as needed. The sleeve and steel forceps can be taken apart after the procedure and autoclaved separately, to maintain sterility.

8.0 Future Recommendations

Although the device that the team created is fully functional and adaptable for a range of different types of forceps, the limited amount of time along with scheduling constraints with our client provided some insurmountable setbacks throughout the development of the product. Suggestions for future work on this device will be discussed in this chapter. These suggestions include creating an industrialized polypropylene mold, gaining feedback from more doctors across different disciplines, and working to create an accurate system of measurements in order to size the device correctly to each doctor's hand comfortably.

8.1 Creating a polypropylene mold

The models that were used as prototypes to perfect the creation of our final device were 3D printed using ABS (acrylonitrile butadiene styrene) in order to most efficiently use our time and budget. Though ABS is relatively cheap and manufacturable in terms of its moldability into different shapes and forms, it is not appropriate to use this type of plastic in a surgical setting where the material will come into direct contact with human tissue. 3D printed ABS can be fragmented due to the manner in which it is printed and there is very little data to suggest what the factor of safety exists when working with 3D printers that can produce ultra-fine particle (UFP) emissions (Stephens, Azimi & Orch, 2013). These particles can remain on the surface of a 3D printed object and can also exist on the micro-surfaces or cracks on the object which can then be transferred into a human subject's body if it were to be used in surgery. It is for this reason that we as a team feel the creation of an industrial polypropylene mold to be used for injection molding would be useful in order to produce the same final product out of a medical grade polypropylene that is approved for use in human patients. This mold would be the casting of the forceps sleeve that the doctor would like to use and would be relatively cheap to produce after the initial cost of creating the mold.

8.2 Doctor sample size and variance

In gaining feedback from Dr. Dunn, our client, we relied on him to give us constructive criticism as to how to make the forceps sleeve be the best fitting adaptation to tissue forceps for him. This caused us to create a final product which was validated by him and which, he felt, was the best that it could be. Future work on this project could include gaining a more comprehensive group of doctors and/or medical school students to provide feedback on various designs in order to produce a wider range of customized tissue forceps sleeves. In this way, a system of customization could be developed to quickly and effectively make models for different hand sizes and comfort preferences to make the device more marketable to a greater range of medical professionals.

8.3 Sleeve Customization

As it was mentioned in previous sections, Dr. Dunn served as our client for our project and our sole model for creating a tissue forceps sleeve that would increase overall ergonomics. This means that the final product we have created uses ergonomic parameters and features that we have defined in the process of development to be customized for Dr. Dunn's personal preference. Because not every doctor or medical professional will have the same opinion of comfort and fit to the hand of their tools, we felt as a team it would be useful to create an accurate system of measurements that can be used to fit the sleeves to the hands of individuals based on their preferences in the future work of the project. After some brief research and experimentation with Dr. Dunn and some dimensional measurements of his hand, we feel that in the future work of this project it would only require a few simple measurements of specific areas of the hand in order to size forceps sleeves to be most comfortable for each unique user. This would include a measurement of the thumb length (TL), which is the distance from the tip of the thumb to the base of the knuckle where the thumb meets the palm, the index length (IL), which is the distance from the tip of the index finger to the point perpendicular to the thumb knuckle, and the hand width (HW), which is the distance from one end of the palm to the other.

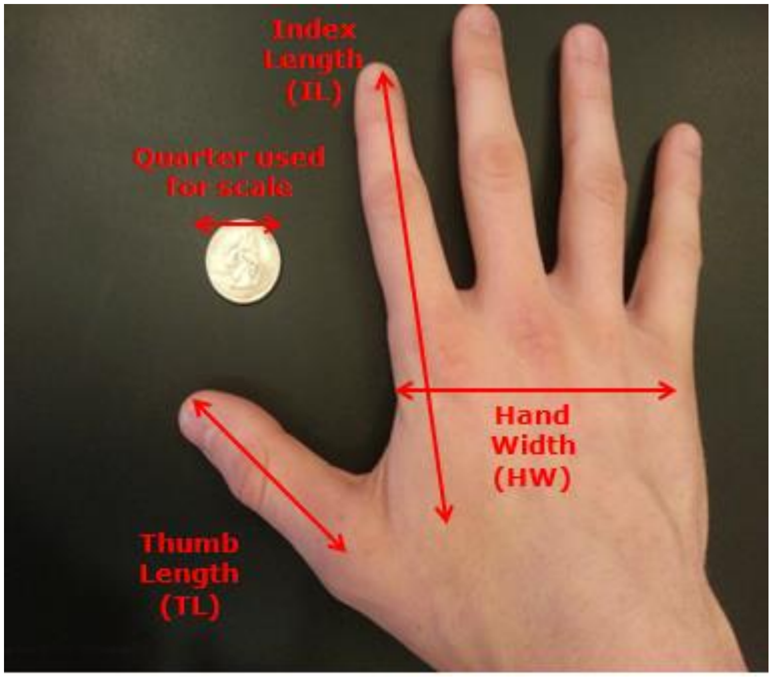


Figure 28: Picture of hand for sleeve customization

Using these measurements, three to five models can be produced from cheap ABS plastic that are 3D printed in order for the user to determine which feels most comfortable for them based on the dimensions they provide. These prototype models can be produced in computer aided design (CAD) software and completed in less than a day. The user can then pick one or two of these prototype models as the ones that they feel fit best. After this they will send their choices back to the team and they will use the model(s) and create a final virtual model in CAD using the features and dimensions selected by the customer from the prototype and send them to an injection molding company to have the final forcep sleeve produced in medical grade polypropylene. As shown in the picture above, these measurements can be taken through a digital image which can make the process of customization even more seamless for the customer and create a viable business with the only outsourced portion of the process being the use of an injection molding facility and the creation of the mold itself.

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Appendices

Appendix A: Pairwise Comparison Charts by Dr. Raymond Dunn

Main Objectives					
	Standardized set of Forceps	**Ergonomics**	**Cost**	**Safety**	**Total**
Standardized set of Forceps	X	0	0.5	1	1.5
Ergonomics	1	X	1	1	3
Cost	0.5	0	X	1	1.5
Safety	0	0	0	X	0

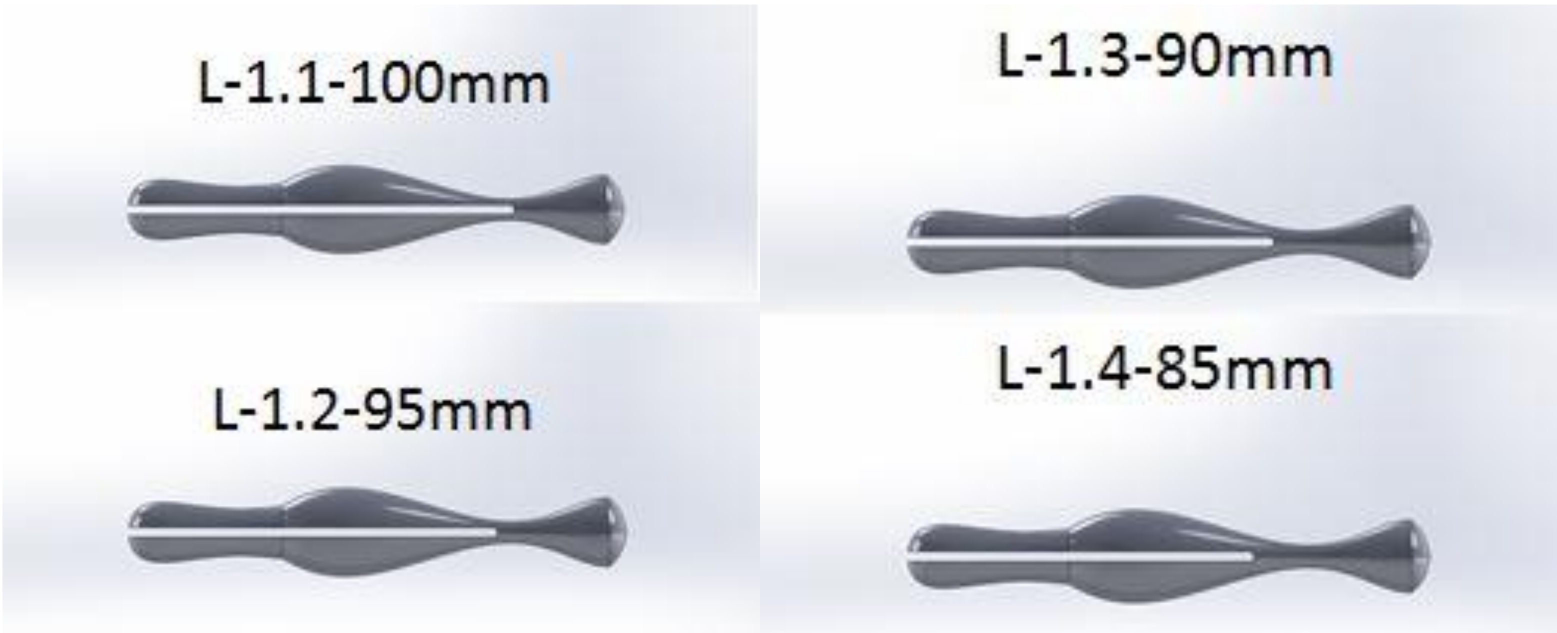
Ergonomic Sub objectives								
	Dimensions	**Weight**	**Grip Location**	**Center of Balance**	**Force Applied**	**Rotational Movement**	**Liner Movement**	**Total**
Dimensions	X	0	0	0	0	0	0.5	0.5
Weight	1	X	0	0	0	0	0.5	1.5
Grip Location	1	1	X	0.5	0.5	0	1	4
Center of Balance	1	1	0.5	X	0.5	0.5	1	4.5
Force Applied	1	1	0.5	0.5	X	0.5	1	4.5
Rotational Movement	1	1	1	0.5	0.5	X	1	5
Linear Movement	0.5	0.5	0	0	0	0	X	1

Appendix B: Gantt Chart

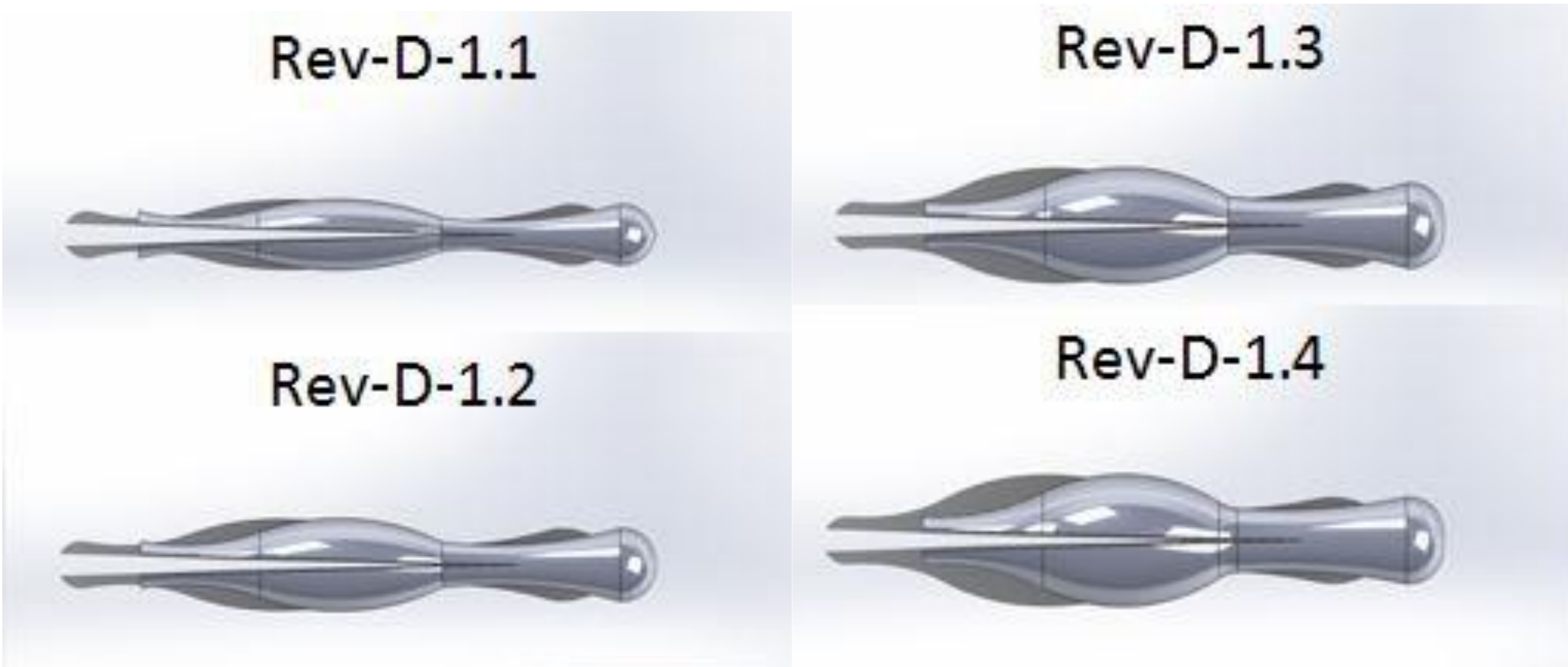
	B Term									C Term							
	28-Oct	4-Nov	11-Nov	18-Nov	25-Nov	2-Dec	9-Dec	16-Dec	23-Dec	13-Jan	20-Jan	27-Jan	3-Feb	10-Feb	17-Feb	24-Feb	3-Mar
Preliminary Data Gathering																	
Observe Surgery																	
Establish Range of Forceps																	
Measure Market Forceps																	
Develop Test Procedures																	
Software																	
SolidWorks Models/ Prototypes																	
FEA of Models																	
Rapid Prototyping						1st Pro											
Analysis of Rapid Prototypes																	
Consultation																	
Umass Lowell																	
Surgeons																	
Testing with Surgeons																	
Advisor meeting Dr. Billiar																	
Advisor meeting Dr. Dunn																	

	D Term						
	17-Mar	24-Mar	31-Mar	7-Apr	14-Apr	21-Apr	28-Apr
Software							
SolidWorks Models/ Prototypes							
FEA of Models							
Rapid Prototyping							
Testing							
Rotational							
Instron 5544							
Clinical Validation							
Consultation							
Client Validation (Dr. Dunn)							
Advisor Meeting Dr. Billiar							
Surgery							
PowerPoint Preparation							

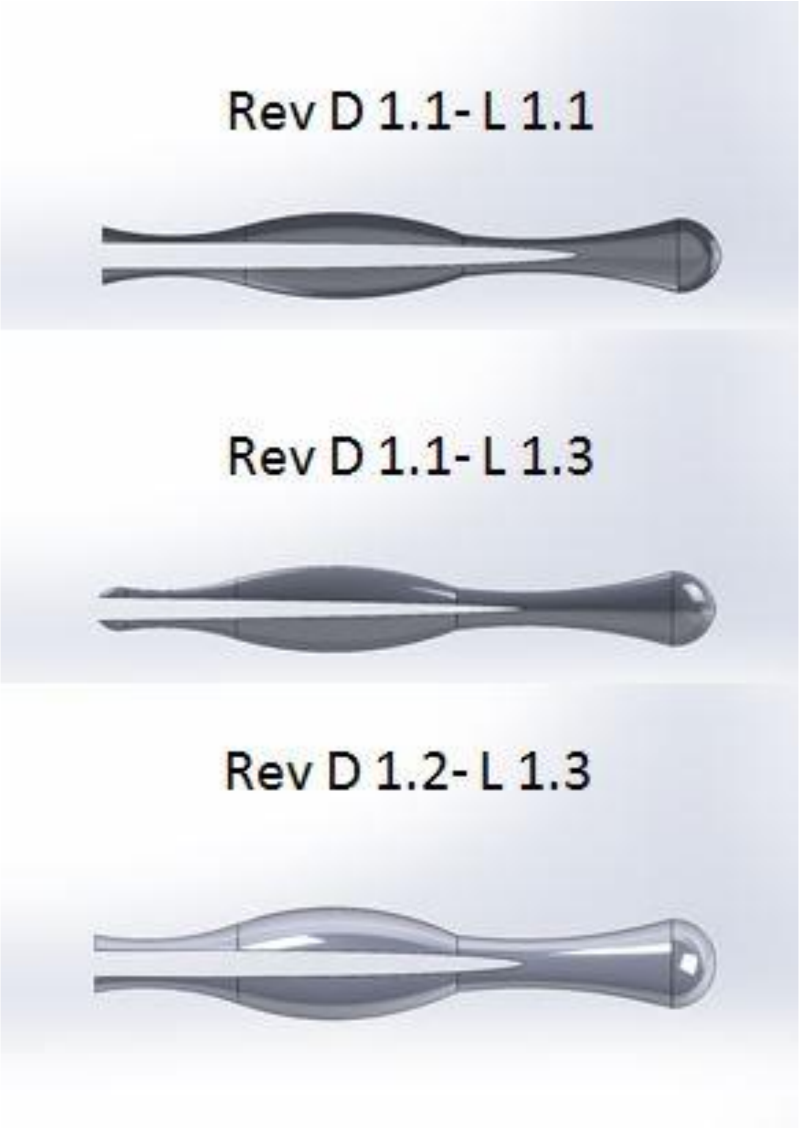
Appendix C: SolidWorks L Series Design



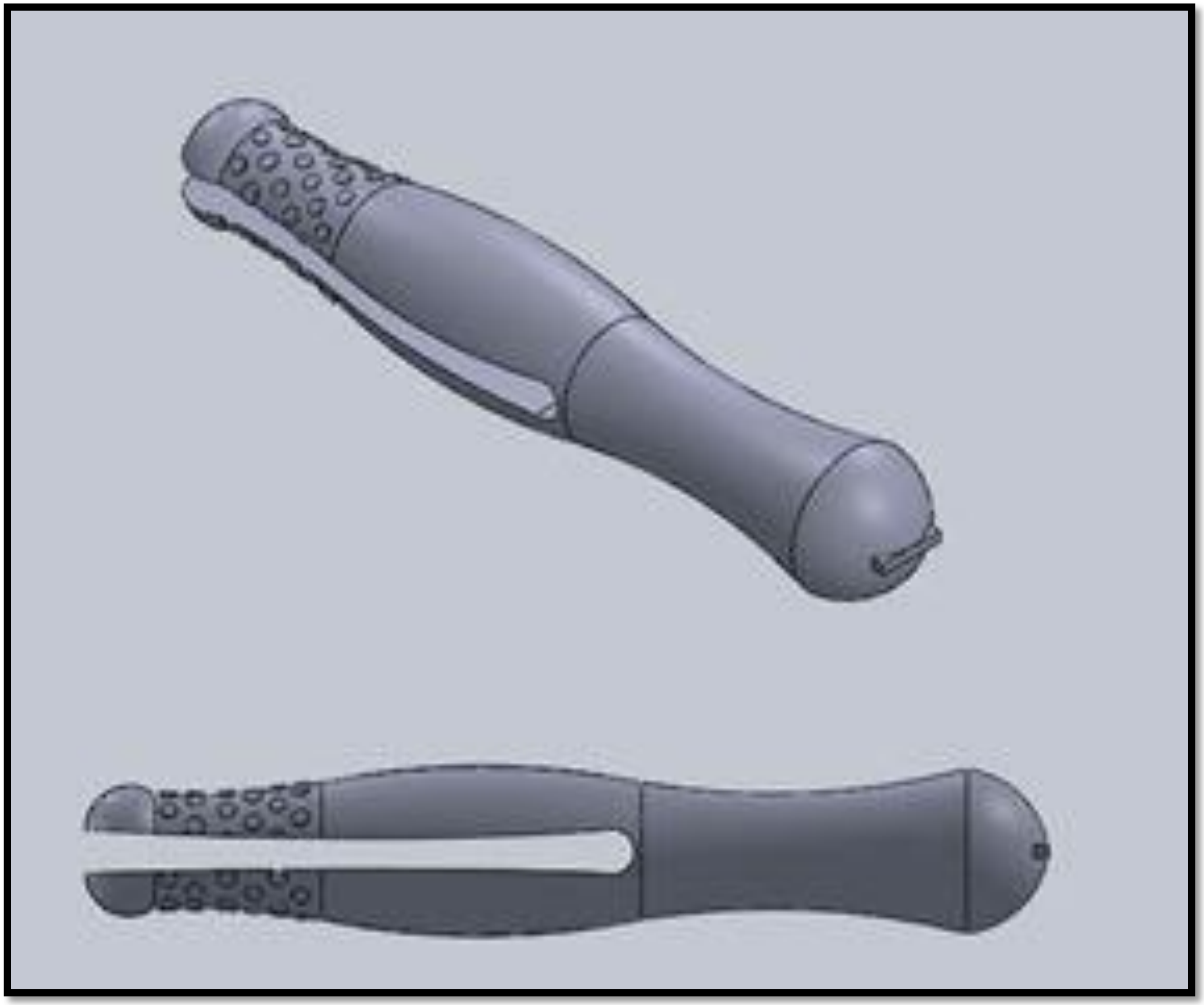
Appendix D: SolidWorks Rev Series Design



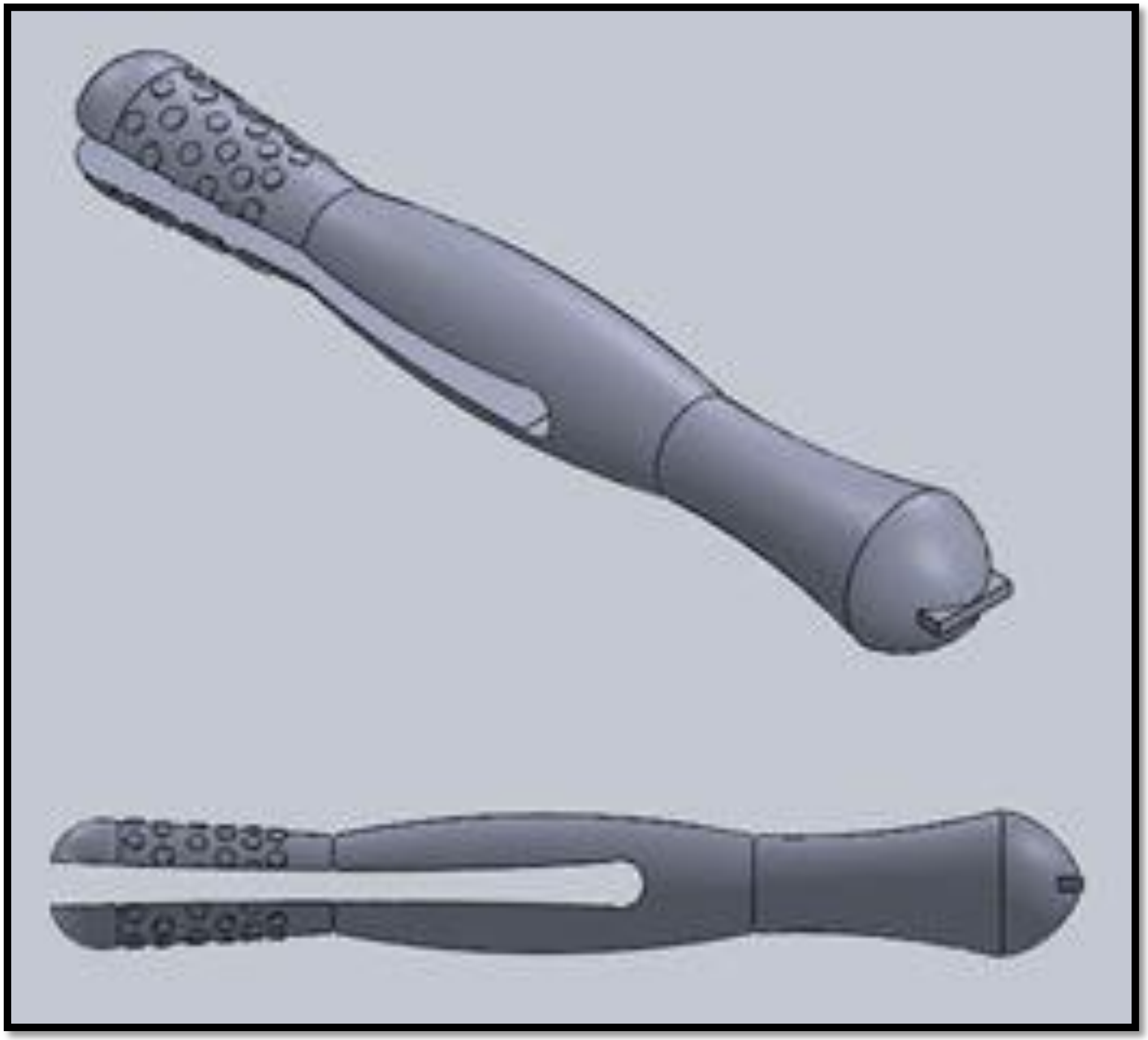
Appendix E: SolidWorks Rev and L Series Combined



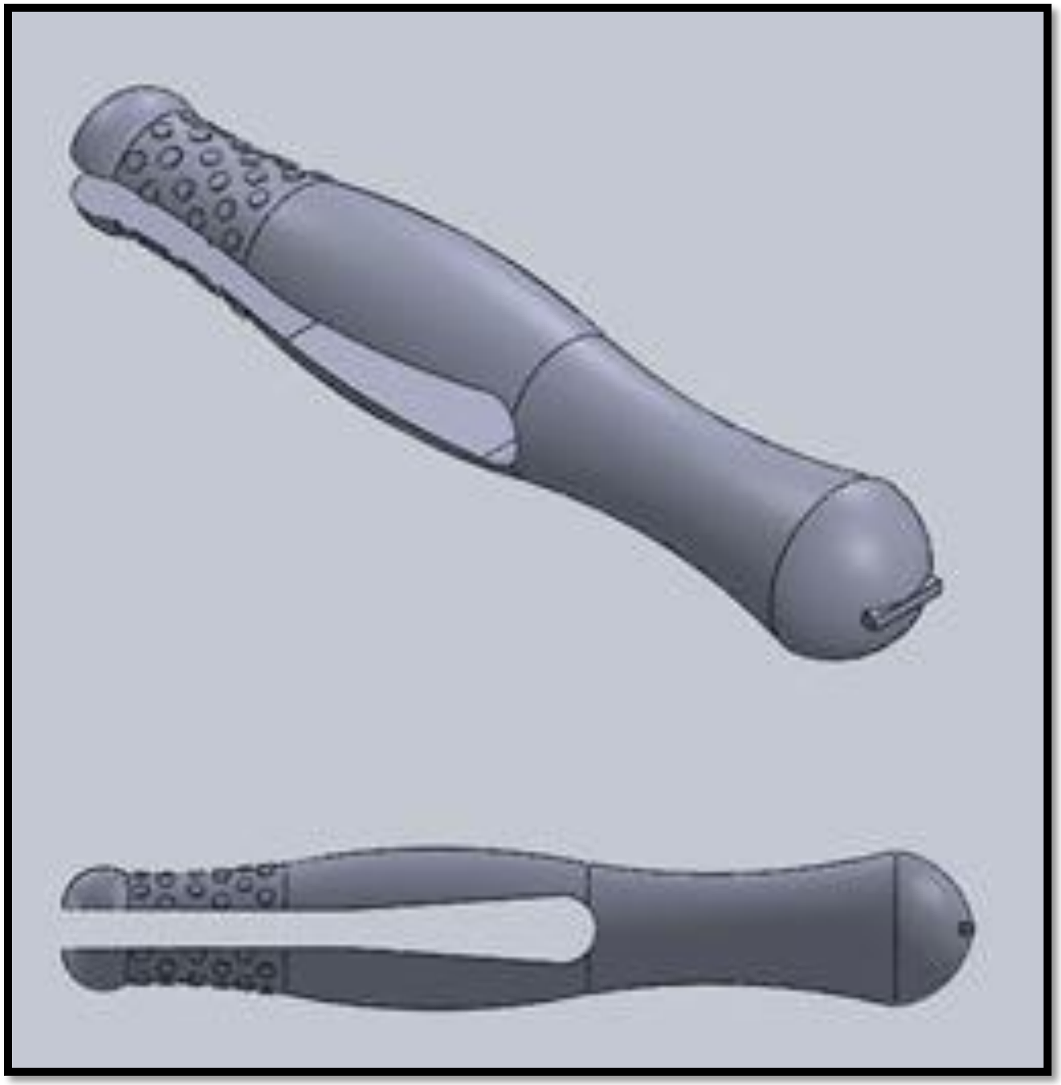
Appendix F: SolidWorks Final Design Mod 4: Correct Length and Diameter



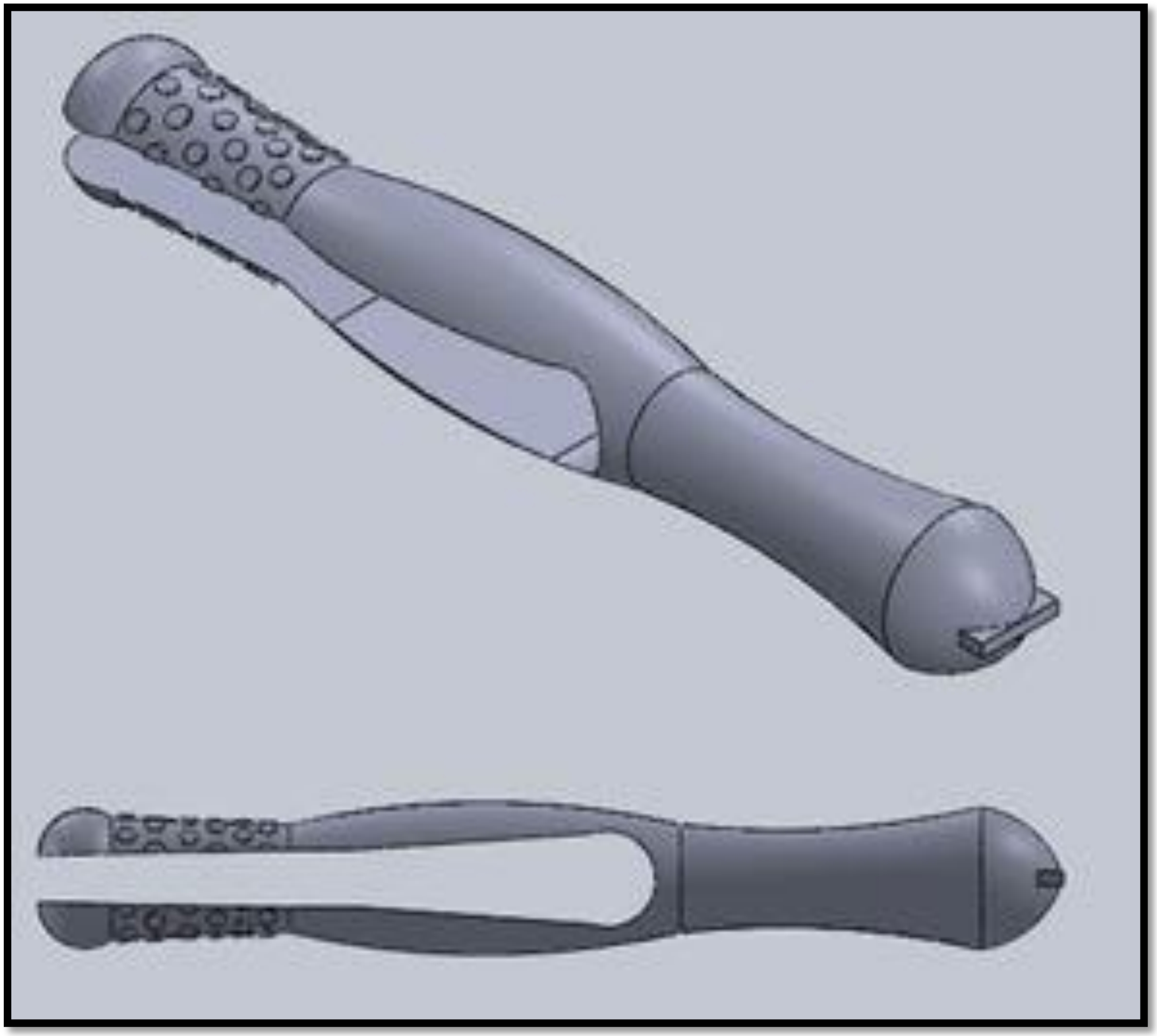
Appendix G: SolidWorks Final Design Mod 5: Reduction in Diameter



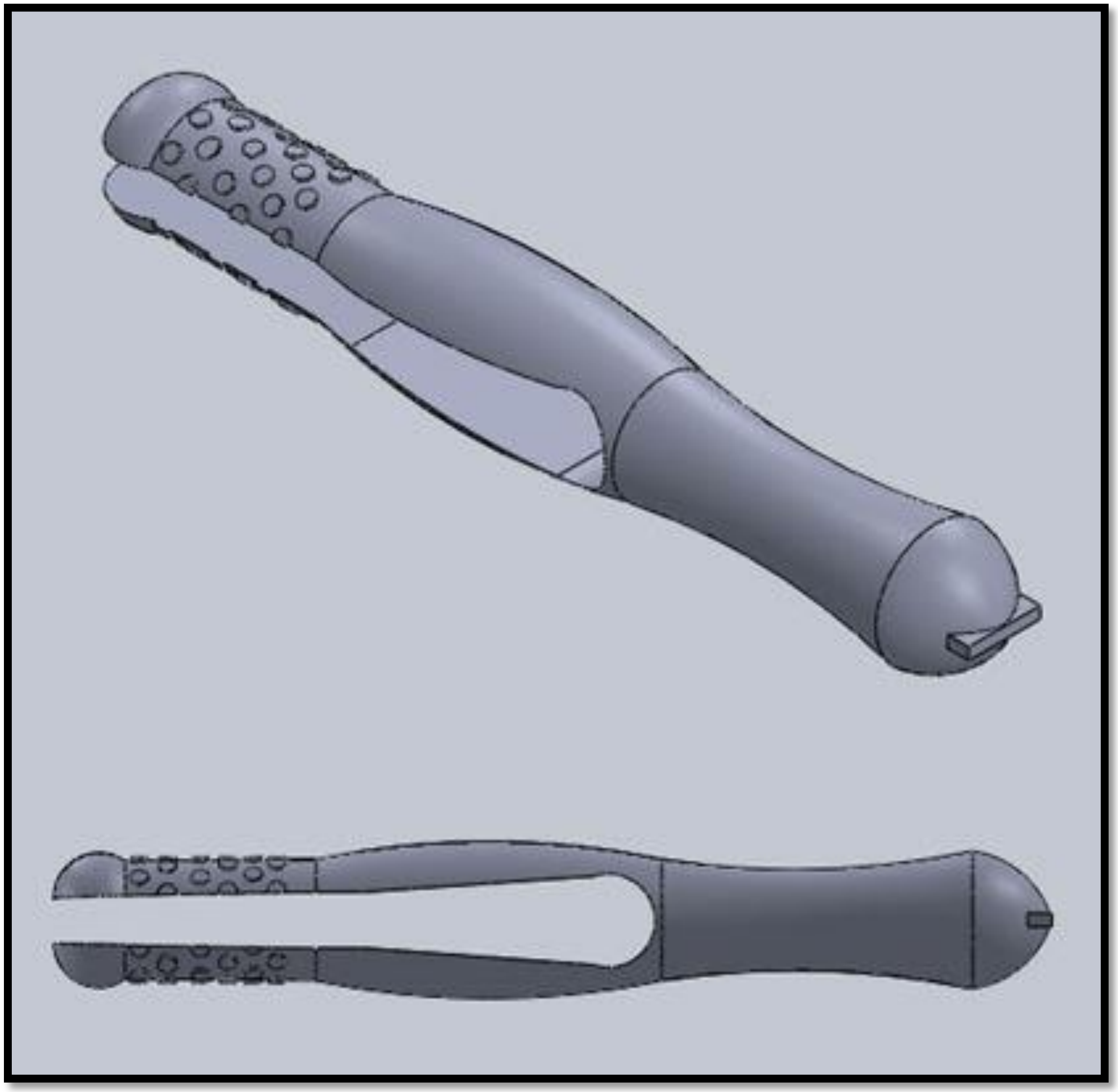
Appendix H: SolidWorks Final Design Mod 6: Increase in Interior Cut



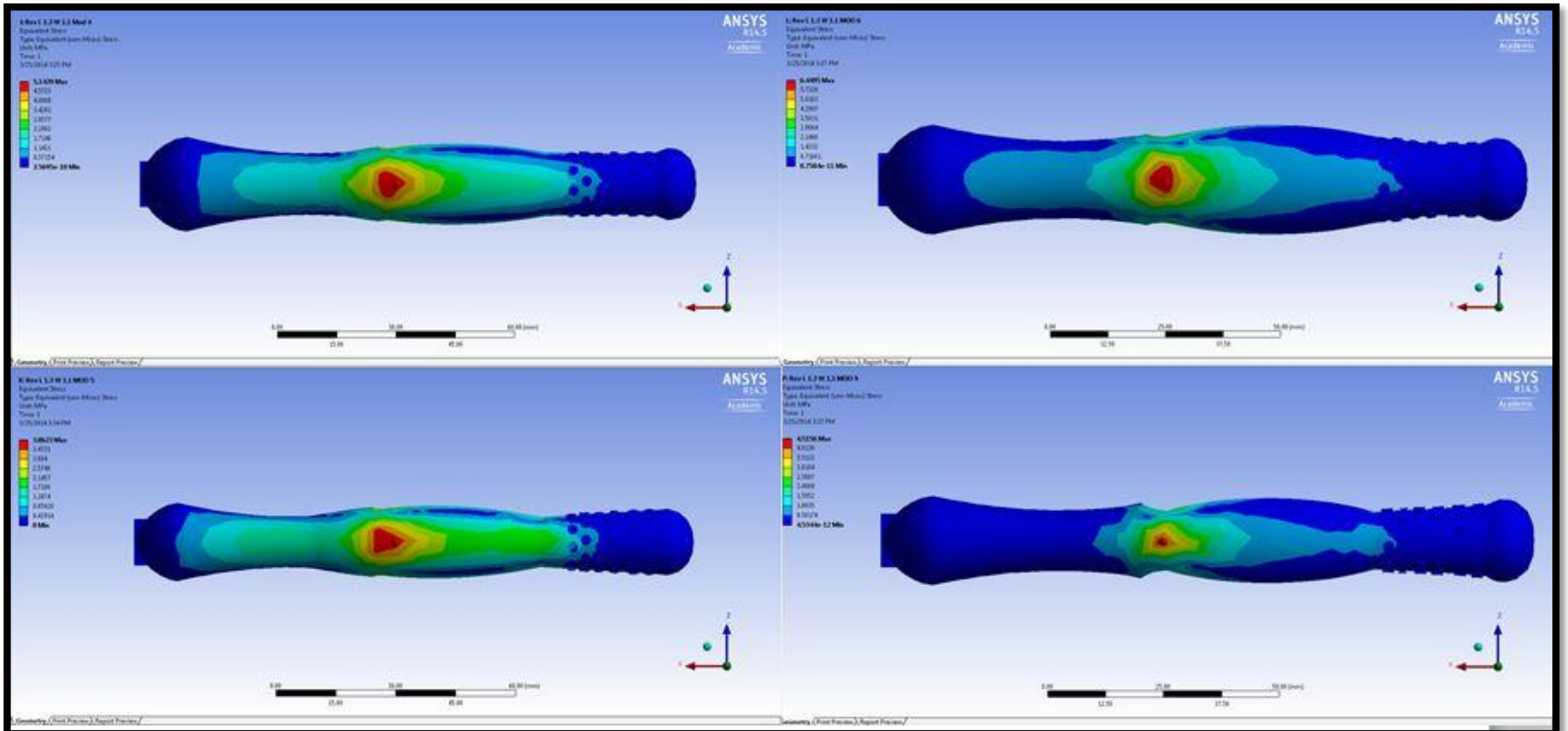
Appendix I: SolidWorks Final Design Mod 9: Combination of Mod 5 and 6 with Minor Alterations



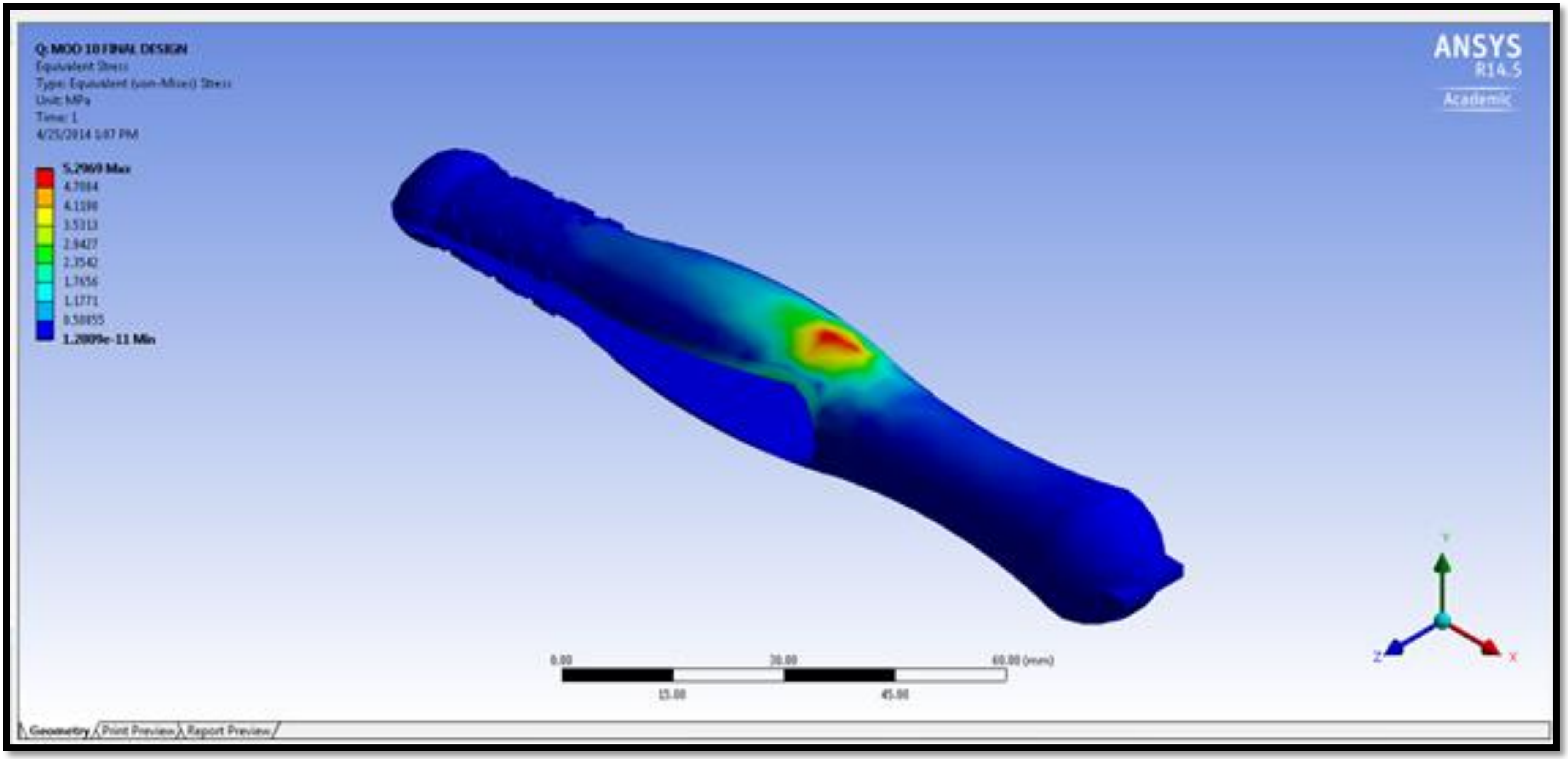
Appendix J: SolidWorks Final Design 10: Design 9 with Improved Ergonomics

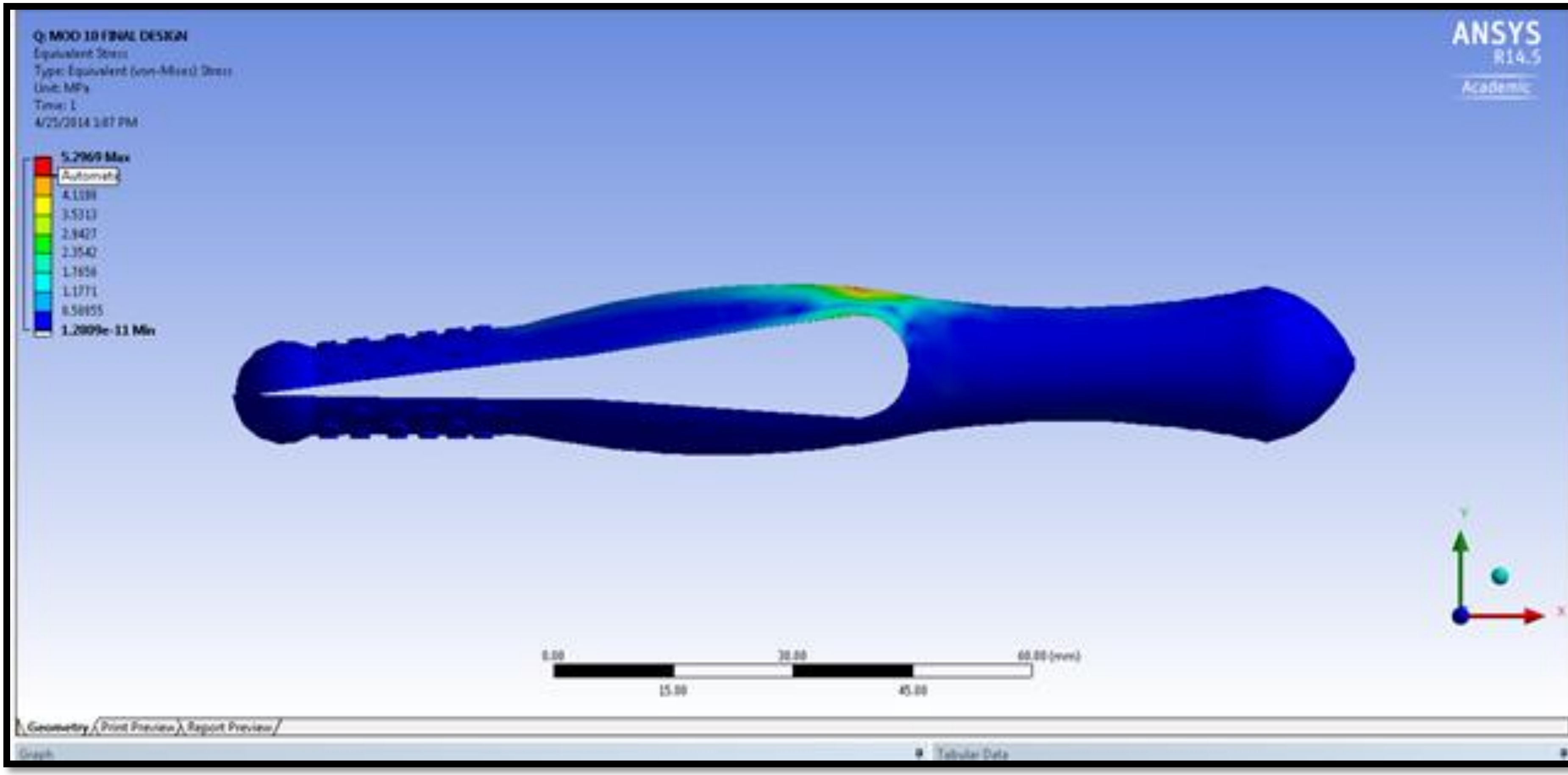


Appendix K: FEA Final Designs Stress Concentrations: Mods 4,5,6,9



Appendix L: FEA Final Design Mod 10 Stress Concentrations




Q: MOD 10 FINAL DESIGN
Equivalent Stress
Type: Equivalent (von-Mises) Stress
Unit: MPa
Time: 1
4/25/2014 1:07 PM
5.2969 Max
4.1198
3.5313
2.9427
2.3542
1.7656
1.1771
0.58855
1.2809e-11 Min
ANSYS
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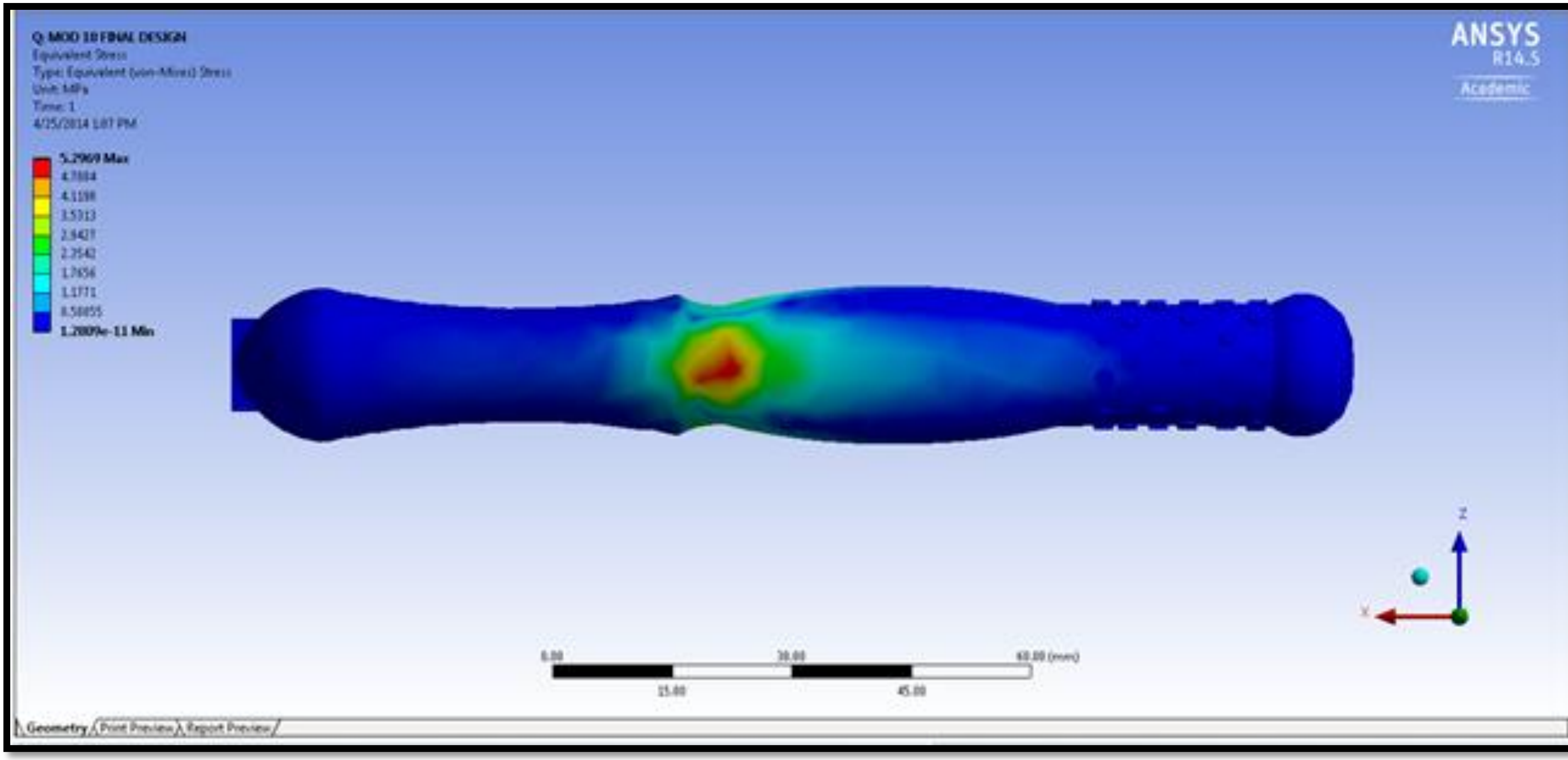
0.00
30.00
60.00 (mm)
15.00
45.00
Geometry
Print Preview
Report Preview
Graph
Tabular Data


Q: MOD 10 FINAL DESIGN
Equivalent Stress
Type: Equivalent (von-Mises) Stress
Unit: MPa
Time: 1
4/25/2014 1:07 PM
5.2969 Max
4.7084
4.1198
3.5313
2.9427
2.3542
1.7656
1.1771
0.58855
1.2809e-11 Min
ANSYS
R14.5
Academic
Z
X
0.00
30.00
60.00 (mm)
15.00
45.00
Geometry
Print Preview
Report Preview

Appendix M: Rapid Prototypes

Appendix N: Final Design Mod 10 Rapid Prototype